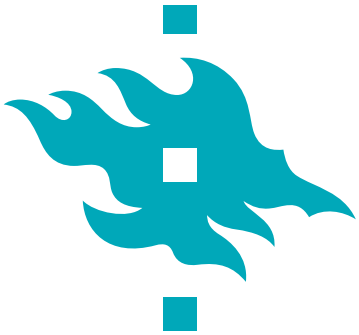

DISSERTATIONES SCHOLAE DOCTORALIS AD SANITATEM INVESTIGANDAM
UNIVERSITATIS HELSINKIENSIS

HEINI LIIMATTA

EFFECTIVENESS OF PREVENTIVE HOME VISITS AMONG COMMUNITY-DWELLING OLDER PEOPLE

DEPARTMENT OF GENERAL PRACTICE AND PRIMARY HEALTH CARE
FACULTY OF MEDICINE
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Effectiveness of preventive home visits among community-dwelling older people

Heini Liimatta

Doctoral Dissertation

To be presented for public discussion with the permission of the Faculty of Medicine of the University of Helsinki, in lecture hall PIII, Porthania, on the 23th of August, 2019 at 12 o'clock.

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There's no place like home.

– Dorothy, The Wizard of Oz

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List of original publications

This dissertation is based on the following publications, which are referred to throughout the text by their Roman numerals:

I. Liimatta H, Lampela P, Laitinen-Parkkonen P, Pitkala KH. Effects of preventive home visits on older people's use and costs of health care services: A systematic review. European Geriatric Medicine 2016;7:571-580.

II. Liimatta H, Lampela P, Laitinen-Parkkonen P, Pitkala KH. Preventive home visits to promote the health-related quality of life of home-dwelling older people: Baseline findings and feasibility of a randomized, controlled trial. European Geriatric Medicine 2017;8:440-445.

III. Liimatta H, Lampela P, Laitinen-Parkkonen P, Pitkala KH. Effects of preventive home visits on health-related quality-of-life and mortality in home-dwelling older adults. Scandinavian Journal of Primary Health Care 2019;37:90-97.

IV. Liimatta H, Lampela P, Kautiainen H, Laitinen-Parkkonen P, Pitkala KH. The Effects of Preventive Home Visits on Older People's Use of Health Care and Social Services and Related Costs. The Journals of Gerontology. Series A, Medical Sciences 2019; https://doi.org/10.1093/gerona/glz139

Abbreviations

ADL	activities of daily living
CGA	comprehensive geriatric assessment
CG	control group
CI	confidence interval
FROP	falls risk for older people
GARS	Groningen Activity Restriction Scale
GDS	Geriatric Depression Scale
GP	general practitioner
HRQoL	health-related quality of life
IADL	instrumental activities of daily living
ICER	incremental cost-effectiveness ratio
IG	intervention group
IQR	interquartile range
MMSE	Mini-Mental State Examination
MNA	Mini Nutritional Assessment
OARS	Older Americans Resources and Services scale
PHV	preventive home visit
QALY	quality-adjusted life-year
QOL	quality of life
RAI	Resident Assessment Instrument
RAI-HC	The interRAI Home-Care Assessment System
RCT	randomized controlled trial

SD	standard deviation
SE	standard error
SRH	self-rated health
VAS	visual analogue scale
WHO	World Health Organization

Abstract

Preventive home visits (PHVs) to support functioning and well-being of older people and to reduce the rates of institutionalization and hospitalization have been studied for decades. The importance of preventive evidence-based effective means increases as the proportion of older people in the population continues to grow. Preventive means to support independence are needed, as many older people wish to continue living at their homes as long as possible. At the same time there is an economic aim: cost-effective means are needed for assessing and managing early the illnesses and disabilities of older people to constrain the growing need for costly hospital care and long periods of institutionalization. PHVs might offer one such intervention. However, findings in PHV studies have been controversial.

In this study, with four sub-studies, we explored the effects of PHVs targeted to home-dwelling older people. In Study I we systematically reviewed the evidence from randomized controlled trials (RCTs) on the effectiveness of PHVs targeted to community-dwelling older people on their functioning, well-being and health-related quality-of-life (HRQoL), mortality and use and costs of healthcare and social services. In Studies II–IV an RCT was carried out to investigate the effects of multiprofessional PHV intervention implementing comprehensive geriatric assessment (CGA) of independent home-dwelling older people in regard to their HRQoL (15-dimensional [15D] measure) and use and costs of healthcare and social services. A new intervention trial was performed due to the lack of studies on effects of multiprofessional PHVs on patient-preferred outcomes (HRQoL), and their cost-effectiveness.

A systematic search of databases (PubMed, Ovid Medline, Cochrane Database, DARE, and Cinahl) supplemented with a manual search of references from earlier reviews was performed in Study I to identify RCTs reporting on the effects of PHV interventions targeted to unselected community-dwelling older populations. Study I review article included PHV trials with focus on use and costs of services and the literature review included a broader selection of RCTs on PHV interventions. Relevant studies were independently rated by three investigators as regards methodological quality and the extracted data was summarized descriptively. Most of the studies were of good or moderate methodological quality and 25 out of 33 studies reported some favourable effects of PHVs, mainly on functioning. These positive effects were produced cost-neutrally, as no differences in total costs between the intervention and control groups were reported.

The present PHV intervention study is an RCT (n = 422) examining the effects of a three-visit multiprofessional PHV programme implementing CGA targeted to home-dwelling older people

randomized into intervention (n = 211) and control (n = 211) groups. The participants in the trial were older people (75 years old or older) living in their homes with no regular home help or care in Hyvinkää municipality, Finland. The intervention group received three home visits delivered by a nurse, a physiotherapist and a social worker.

In Study II we reported the baseline data and feasibility of the intervention. Randomization was successful, with the intervention and control groups being balanced at baseline. PHV intervention was found to be feasible among the home-dwelling older people. There were no drop-outs during the intervention and feedback at the one-year follow-up was mostly favourable. Only 13% of the responders found the home visits not to be beneficial.

Study III concerned the effects of PHV intervention on the primary outcome of the trial. Measured using the 15D instrument, HRQoL in the intervention group declined significantly more slowly, the difference between groups in changes after one year being -0.015 (95% CI -0.029 to -0.0016; p = 0.028 adjusted for age, sex, and baseline value). However, the effect was diluted after the home visits were discontinued, and there was no significant difference between the groups at the two-year follow-up. There were no differences in mortality between the groups.

Study IV concerned the use and costs of healthcare and social services of the participants and a cost-utility analysis. There were no significant differences in the use of healthcare and social services of the participants at baseline or during follow-up, or in the total costs of healthcare and social services. There were no significant differences in quality-adjusted life-years (QALYs) gained between the groups. However, the cost-utility analysis showed 60% of the incremental cost-effectiveness ratio (ICERs) in the "dominant" quadrant of the cost-effectiveness plane, suggesting that the intervention might be both more effective and less costly compared with usual care. There were no reported adverse effects of the intervention.

To conclude, the available literature provides evidence for some positive effects of PHVs on functioning, HRQoL and mortality of older people, although these findings remain controversial. These favourable effects of PHV intervention were produced cost-neutrally. There is some evidence that PHV interventions are cost-effective, but more research is needed. A multiprofessional PHV intervention programme implementing CGA supported the HRQoL of older people during one-year of follow-up, although the effect became diminished once the visits were discontinued. No significant differences between the groups in costs of healthcare and social services were detected. Cost-utility analysis suggested that the intervention might be cost-effective without accruing increased costs.

Tiivistelmä

Ennaltaehkäiseviä kotikäyntejä iäkkäiden toimintakyvyn ja hyvinvoinnin tukemiseksi sekä pitkäaikaishoidon tarpeen ja sairaalahoitojen vähentämiseksi on tutkittu jo useamman vuosikymmenen ajan. Iäkkäiden osuus koko väestöstä kasvaa kiihtyvää vauhtia, ja useat iäkkäät haluavat asua mahdollisimman pitkään omassa kodissaan, joten heidän itsenäisyyttään tukevia ennaltaehkäiseviä keinoja kaivataan. Iäkkäiden toimintakyvyn heikkenemisen ja sairauksien aikaiseen tunnistamiseen ja hoitamiseen tarvitaan kustannusvaikuttavia keinoja, jotta pystytään hallitsemaan kasvavia sairaalahoidon ja pitkäaikaishoidon kustannuksia. Ennaltaehkäisevät kotikäynnit saattaisivat olla yksi keino edellämainittujen tavoitteiden saavuttamiseen, mutta aiempien tutkimusten tulokset niiden tehosta ovat olleet ristiriitaisia.

Tutkimus sisältää neljä osatyötä joiden tarkoituksena on tutkia ennaltaehkäisevien kotikäyntien vaikuttavuutta iäkkäillä. Ensimmäisen osatyön (I) tavoitteena oli selvittää ennaltaehkäisevien kotikäyntien vaikuttavuutta kotonaan asuvien iäkkäiden toimintakykyyn, hyvinvointiin ja terveyteen liittyvään elämänlaatuun, kuolleisuuteen sekä terveys- ja sosiaalipalveluiden käyttöön ja kustannuksiin aiheesta julkaistujen satunnaistettujen kontrolloitujen tutkimusten perusteella. Osatöissä II-IV tarkasteltiin satunnaistetun kontrolloidun tutkimuksen avulla moniammatillisten ennaltaehkäisevien kotikäyntien vaikuttavuutta itsenäisesti kotonaan asuvien iäkkäiden terveyteen liittyvään elämänlaatuun 15D mittarilla ja heidän terveys- ja sosiaalipalveluiden käyttöönsä sekä kustannuksiin hyödyntäen moniammatillista, kokonaisvaltaista geriatrista arviointia.

Ensimmäinen osatyö on systemaattinen katsaus, jota varten toteutettiin kirjallisuushaku käyttäen PubMed, Ovid Medline, Cochrane Database, DARE ja Cinahl tietokantoja ja aiempien katsausten kirjallisuusviitteitä. Katsaukseen hyväksyttiin mukaan tutkimukset, jotka olivat satunnaistetulla kontrolloidulla asetelmalla tehtyjä ja koskivat kotona asuville iäkkäille ihmisille suunnatujen ennaltaehkäisevien kotikäyntien vaikutuksia. Kolme riippumatonta tutkijaa arvioivat tutkimusten metodologisen laadun, ja tuloksia tarkasteltiin systemaattisesti kuvaillen. Suurin osa tutkimuksia oli metodologiselta laadultaan vähintään kohtalaisia, ja 22 tutkimusta 33:sta raportoi ennaltaehkäisevien kotikäyntien tuottaneen positiivisia vaikutuksia, enimmäkseen toimintakykyyn. Tutkimukset eivät raportoineet eroja palveluiden kokonaiskustannuksissa interventio- ja kontrolliryhmien välillä, joten voidaan todeta, että positiiviset vaikutukset tuotettiin kustannus-neutraalisti.

Aikaisempien tutkimusten perusteella tarvittiin lisätutkimusta moniammatillisten ennaltaehkäisevien kotikäytien vaikutuksista terveyteen liittyvään elämänlaatuun, sekä niiden kustannusvaikuttavuudesta. Ennaltaehkäisevien kotikäyntien vaikuttavuutta ei aikaisemmin ole tutkittu Suomessa. Suomessa toteutettu satunnaistettu, kontrolloitu tutkimus (n = 422) selvitti kolmesta moniammatillisesta ennaltaehkäisevästä kotikäynnistä koostuvan intervention vaikuttavuutta itsenäisesti kotona asuvilla iäkkäillä ihmisillä. Tutkittavat olivat 75 vuotta täyttäneitä hyvinkääläisiä, jotka asuivat kodeissaan ilman säännöllistä kotiapua tai -hoitoa. Heidät satunnaistettiin interventio- (n = 211) ja kontrolliryhmiin (n = 211). Interventioryhmälle tehtiin kolme kattavaa geriatrista arviointia hyödyntävää ennaltaehkäisevää kotikäyntiä hoitajan, fysioterapeutin ja sosiaalityöntekijän toimesta.

Osatyö II kuvaa tutkittavien lähtötilanteen sekä intervention toteutettavuuden. Interventio- ja kontrolliryhmät olivat samankaltaiset lähtötilanteessa. Ennaltaehkäisevistä kotikäynneistä yhtään ei jäänyt tekemättä, ja interventio todettiin mahdolliseksi toteuttaa kotona-asuvien ikääntyneiden keskuudessa. Palaute tutkittavilta yhden vuoden seurannassa oli pääosin positiivista ja vain 13% vastaajista totesi, ettei kotikäynneistä ollut heidän mielestään hyötyä.

Osatyö III raportoi tutkimuksen päätulokset, eli intervention vaikuttavuutta terveyttä koskevaan elämänlaatuun 15D mittarilla. Yhden vuoden seurannassa interventioryhmän elämänlaatu 15D mittarilla mitattuna oli laskenut merkitsevästi hitaammin kuin kontrolliryhmässä, ryhmien välisen eron ollessa -0.015 (95% CI -0.029 to -0.0016; $p = 0.028$ vakioituna iän, sukupuolen ja lähtötilanteen arvon mukaan). Ero kuitenkin kapeni kotikäyntien loputtua, eikä kahden vuoden seurannassa ryhmien välillä ollut enää merkitsevää eroa. Kuolleisuudessa ei ryhmien välillä todettu eroa.

Osatyö IV raportoi tutkittavien terveys- ja sosiaalipalveluiden käytön ja kustannukset sekä kustannusvaikuttavuusanalyysin tulokset. Lähtötilanteessa tai seurannan aikana tutkittavien ryhmien välillä ei ollut eroja palveluiden käytössä tai kustannuksissa. Ryhmien välillä ei todettu eroa laatupainotetuissa elinvuosissa (QALY). Kuitenkin kustannusvaikuttavuusanalyysi osoitti että 60% arvioidusta inkrementaalisesta kustannusvaikuttavuussuhteesta (ICER) osui kustannusvaikuttavuutta kuvaavassa tasossa “dominantille” neljännekselle, viitaten siihen, että tutkittu interventio saattaa olla sekä tehokkaampi että edullisempi kuin tavanomainen hoito.

Interventioryhmän tutkittavista kukaan ei jäänyt pois tutkimuksesta intervention aikana. Haittavaikutuksia interventiosta ei raportoitu.

Tutkimusten mukaan ennaltaehkäisevät kotikäynnit iäkkäille tuottavat positiivisia vaikutuksia heidän toimintakykyynsä, elämänlaatuunsa ja kuolleisuuteensa, mutta tulokset ovat yhä ristiriitaisia. Nämä positiiviset vaikutukset saavutettiin kustannuksia lisäämättä. Lisää tutkimuksia ennaltaehkäisevien kotikäyntien kustannusvaikuttavuudesta tarvitaan. Moniammatilliset, kattavaa geriatrista arviointia hyödyntävät ennaltaehkäisevät kotikäynnit tukivat iäkkäiden terveyteen liittyvää elämänlaatua yhden vuoden seurannassa, mutta vaikutus väheni kun kotikäynnit lopetettiin. Ryhmien välillä ei havaittu eroa terveys- ja sosiaalipalveluiden kustannuksissa. Kustannusvaikuttavuusanalyysin mukaan interventio voisi olla kustannusvaikuttava.

1 Introduction

An aging population challenges societies as to how best to offer social and healthcare services to older adults. The population aged 65 years and older is sharply increasing in developed countries, and the fastest growing proportion is that covering the oldest old (80+). This will have major impact on healthcare expenditure, which is particularly driven by the amount of older people receiving long-term care in institutions or at home (European Commission 2005). The prevalence of disorders associated with aging will increase as the population of over 65-year-olds grows in numbers. Multimorbidity increases with age, and it is associated with disability, dependence, impaired quality of life (QOL) and mortality. Multimorbidity increases hospital admissions; therefore care coordination and addressing the problems early are essential (Prince et al. 2015).

Effective *primary, secondary* and *tertiary prevention* targeted at older people is aimed at reducing disease burden and disabilities (Prince et al. 2015). *Primary prevention* is aimed at preventing the onset of a disease and maintaining health and functioning by means such as enhancing healthy nutrition, physical activity, treatment of hypertension and avoidance of cigarette smoking. When primary prevention is successful, it reduces loss of function, suffering and use and costs of healthcare and social services. *Secondary prevention* is aimed at identifying an established disease at its presymptomatic or early stage, and treating, for example, cardiovascular risk factors in patients with known heart disease or diabetes (Rubenstein et al. 1998). *Tertiary prevention* is aimed at reducing symptoms and preventing complications of an existing disease, maintaining functioning and QOL and minimizing suffering of individuals with existing disabilities and syndromes (Pitkala et al. 2018b).

Several well-designed prevention studies have proven the efficacy of many preventive interventions, and evidence supports preventive measures targeted to older people in many areas of geriatrics (Rubenstein et al. 1998). Prevention of cardiovascular diseases (including anticoagulation to prevent strokes, exercising and healthy nutrition) has been shown effective on older people (Allen et al. 2017, Estruch et al. 2018, Sandar et al. 2014). In addition, examples of many areas where evidence suggests favourable effects of preventive actions on older peoples' health, functioning and QOL include healthy nutrition with adequate vitamin D and protein intake, exercising to prevent mobility disabilities, cognitive training and alleviating loneliness (Bischoff-Ferrari et al. 2004, Pahor et al. 2014, Suominen et al. 2015). This also supports implementation of multifaceted prevention interventions and programmes, applying comprehensive geriatric

assessment (CGA) and further measures targeted to individual needs of older adults (Johansson et al. 2009, Lundqvist et al. 2018, Stuck et al. 2002).

Considering geriatric syndromes, an important target group for preventive measures are multimorbid older people. Evidence from prevention studies supports implementation of interventions with CGA by a multi-professional team (Beswick et al. 2008). CGA has been shown to enhance functioning, to postpone institutionalization and to reduce mortality. There is strong evidence of its effect in tertiary prevention (Stuck et al. 2002). If older adults' functioning and QOL can be maintained closer to their end of life, there may be more value to their late-life years even if death cannot be postponed. Therefore, the compression of morbidity could be successful, even without the gain of a longer life (Allen et al. 2017).

Preventive means targeted at supporting older adults' functioning and QOL have been hoped to postpone institutionalization and to prevent hospitalization (Markle-Reid et al. 2006, Stuck et al. 2002). Preventive home visits (PHVs) for older people have been studied for decades. Some studies of PHVs targeted to older people have shown favourable effects on functioning, well-being, mortality (Fagerström et al. 2009, Stuck et al. 2002) and institutionalization (Elkan et al. 2001). Furthermore, the results of some studies suggest in particular that PHV intervention involving CGA, and with sufficient intensity of visits and follow-up could produce favourable outcomes (Stuck et al. 2002). However, the results of studies concerning their effectiveness on clinical outcomes and cost-effectiveness remain controversial (Mayo-Wilson et al. 2014, Tappenden et al. 2012). In particular, research on the cost-effectiveness of PHV interventions has lagged behind (Tappenden et al. 2012).

This study was aimed at systematically evaluating the evidence from randomized controlled trials (RCTs) of PHVs on home-dwelling older adults. In the systematic review we explored PHV effects on clinical outcomes such as functioning, health-related quality of life (HRQoL) as well as use and costs of health- and social services. In addition, an RCT was performed in Hyvinkää municipality to explore the effects of a multi-professional PHV intervention programme on older adults' HRQoL and use and costs of health- and social services. There was a need for a new intervention trial due to a lack of multiprofessional home visit studies which included the social approach (van Kempen et al. 2012), and only few studies using patient-preferred outcomes (quality-of-life) (Brettschneider et al. 2015) and exploring cost-effectiveness of PHV interventions (Corrieri et al. 2011, Metzelthin et al. 2015, Tappenden et al. 2012). No effectiveness studies on PHVs had been performed in Finland earlier.

2 Review of the literature

2.1 Preventive home visits (PHVs)

2.1.1 *Definitions*

Preventive home visits are various types of intervention targeted at community-dwelling people. They may include interventions targeted on single health problems or diagnoses such as falls or stroke (Elley et al. 2008, Green et al. 2002) or they may be used to screen and manage early geriatric syndromes of various types (Imhof et al. 2012, Stuck et al. 2000). Therefore, researchers have not agreed on any one definition of preventive home visits. Although term PHV is mostly used in literature similar interventions have also been called health-promotion (Behm et al. 2016), case management (Granbom et al. 2017) and proactive care interventions (Blom et al. 2018). The term PHV is used in this dissertation to refer to all interventions fulfilling following definitions. This dissertation is focused on multidimensional PHVs targeted to independent home-dwelling older adults.

The aim of PHVs is to increase independence, well-being and QOL using primary, secondary and tertiary prevention activities delivered by healthcare professionals. PHV interventions aim to prevent negative long-term outcomes such as mortality and institutionalization (Mayo-Wilson et al. 2014). The target populations and interventions in PHV studies have been varied. Some trials have been focused only on one diagnosed illness or a risk factor, such as falls (Corrieri et al. 2011), whereas others have been focused on unselected home-dwelling older populations (Bouman et al. 2008b, Mayo-Wilson et al. 2014, Toljamo et al. 2005). The intervention deliverers have also varied from a single nurse to multi-professional teams of experts. In practice the interventions vary greatly. In some interventions the interventionist just delivers specific information or health education, whereas others implement extensive interventions such as CGA (Mayo-Wilson et al. 2014, Stuck et al. 2002; see chapter 2.1.2. p. 22 for definition of CGA). The variety of PHV definitions and interventions is also mirrored in the diversity of studies included in the systematic reviews (Beswick et al. 2008, Bouman et al. 2008b, Corrieri et al. 2011, Huss et al. 2008, Markle-Reid et al. 2006, Mayo-Wilson et al. 2014, Stuck et al. 2002, Toljamo et al. 2005).

A systematic review defined PHVs as: "… visits to older people living in the community, which are aimed at multidimensional medical, functional, psychosocial, and environmental evaluation of their problems and resources. This evaluation results in specific recommendations aimed at reducing or treating the observed problems and preventing new ones. Follow-up visits are included for the

implementation of the intervention plan" (Bouman et al. 2008b). Based on earlier literature and this definition, the present studies are focused on multidimensional PHV programmes targeted to an unselected home-dwelling older population. Therefore, the literature review does not include studies on follow-up home visits directly related to recent hospital discharge, or studies on condition-specific interventions, for example exclusively targeted to people with one specific disease or diagnosis, fall prevention or cognitive function.

PHVs are part of national healthcare policy as regards preventive and proactive primary care for older adults in several countries, e.g. Denmark, the United Kingdom and Australia (Metzelthin et al. 2015). However, in most countries PHVs are not used nationwide in the healthcare of older people, and in some countries only some municipalities offer PHVs as part of primary-care services (Tøien et al. 2018). This includes all Nordic countries except Denmark where the PHVs have been provided by law since the 1990s (Finlex 2012). Exploring the extent of use of PHVs in primary care is challenging due to the varied target groups of older people and varied ways of implementing the intervention.

In Finland municipalities have offered PHVs to varying degrees. Finnish National Institute for Health and Welfare reported 64% of municipalities providing PHVs in 2009. However, only half of all municipalities in Finland had answered the survey (Seppänen et al. 2009). The PHVs were provided regularly in 80% of these municipalities and others provided them as shorter projects (Seppänen et al. 2009). Mostly the PHVs have been targeted to older people 75 years or 80 years old, and most interventions included a single home visit (Seppänen et al. 2009). Surveys and qualitative thesis studies in Finland have indicated that older people and professionals find the PHVs useful (Kaijansinkko 2013, Seppänen et al. 2009), which is in line with studies from other Nordic countries (Tøien et al. 2018, van Kempen et al. 2012).

However, there is a lack of effectiveness and cost-effectiveness studies in Finland, and this evidence has been based on international studies (Kaijansinkko 2013, Toljamo et al. 2005). In addition, many of the PHV interventions offered have lacked in structure of the interventions, education of the interventionists, and follow-up, and multiprofessional teams have been poorly utilized (Kaijansinkko 2013, Seppänen et al. 2009). The data on complex health care interventions should be considered in the context of underlying social and health care system (Craig et al. 2008). Of the studies performed in Nordic countries and included in the literature review all four studies performed in Sweden produced some favourable effects (Behm et al. 2016, Granbom et al. 2017, Gustafsson et al. 2012, Sahlen et al. 2006), whereas three studies performed in Denmark did not

show as favourable results (Gunner-Svensson et al. 1984, Hendriksen et al. 1984, Sorensen et al. 1988; Table 5; chapter 2.3). However, comparison of these studies is problematic due to heterogeneity as the Danish studies have been performed notably earlier.

Older people see PHVs as an important service for them. In a recent study, older people stated that PHVs support their ability to have a good life and to live at home (Tøien et al. 2018). However, contradictory findings on PHVs in the literature are likely to explain why they are not widely in use as a part of primary care services. It is still unclear who would benefit the most from PHVs and what are the most important features of the intervention that should be included in PHV programmes to be effective (Mayo-Wilson et al. 2014). There is some evidence that PHVs based on CGA are more effective than those based on narrower assessment (Stuck et al. 2002, Huss et al. 2008). Sufficient follow-up with support for participants has also been seen to be important for favourable effects and their stability at follow-up (Stuck et al. 2002). However, no other clear factors have been found to be key features in successful interventions (Stuck et al. 2002, Markle-Reid et al. 2006, Mayo-Wilson et al. 2014). The active contents of PHVs have been questioned in some reviews and there has been argumentation that resource-demanding processes should be replaced with more efficient services (Markle-Reid et al. 2006, Mayo-Wilson et al. 2014). Furthermore, there is still a scarcity of studies on the cost-effectiveness of PHVs (Mayo-Wilson et al. 2014, Metzelthin et al. 2015, Tappenden et al. 2012). Thus, PHVs are not commonly recommended as a nationwide service for assessing older people (Mayo-Wilson et al. 2014).

Table 1 describes terms commonly used in PHV studies and some examples of their dimensions and measures used.

Table 1. Terms commonly used in preventive home visit (PHV) literature and their definitions in this context.

Term	Definition	Examples of dimensions	Example(s) of means and measures used in the literature
Home visit	A visit by a professional to the person's own home or living facility, containing assessment (Bouman et al. 2008b, Muntinga et al. 2016)	Education, information, treatment, rehabilitation, support and help to the person visited	CGA
Preventive, prevention	Actions aimed to maintain health and functioning, prevent onset of a disease, screen and treat diseases at their early stage, and reduce suffering, loss of function and complications in diseases (Rubenstein et al. 1998). (See page 15.)	Blood pressure, other cardiovascular risk factors, nutrition, functioning Education, information, support, coaching self-management	Blood pressure measurement MNA (Guigoz et al. 2002) MMSE (Folstein et al. 1975) Barthel index (Mahoney et al. 1965) Lawton (Lawton et al. 1969)
Health promotion	The process of enabling people to improve their health and to increase control over it, moving beyond a focus on individual behaviour towards a wide range of social and environmental interventions (Ford et al. 2017, WHO 2018)	Cardiovascular risk factors, nutrition, physical, cognitive and social functioning, environment Education, information, support	Blood pressure measurement MNA (Guigoz et al. 2002) MMSE (Folstein et al. 1975) Barthel index (Mahoney et al. 1965) Lawton (Lawton et al. 1969)
CGA	Multi-dimensional, systematic, holistic and multidisciplinary approach to assessment and care of older people. Aims to identify medical, social and functional needs, and develop a co-ordinated care plan to meet assessed needs (Parker et al. 2018). (See page 22.)	Physical, cognitive, social functioning, frailty, falls, home safety, environment Diseases, nutrition, medication Person's own values and aims (See page 23.)	RAI (Hirdes et al. 2008, Morris et al. 1999, Morris et al. 2013)
Multiprofessional intervention	An intervention delivered by a multiprofessional team in which the professionals work side by side contributing their expertise to the team with a focus on the subject of the intervention and his/her goals and needs (Webster 2002, Hammick et al. 2009). (See page 26.)	Screening, observation and evaluation Guidance, support, recommendation for further treatment and other services Systematic follow-up; Individual aims and goals (Fagerström et al. 2009) (See page 26.)	Semistructured interviews (Kvale et al. 2007) Interviews, focus groups, log books, field notes, documents, photos, video, audio
Multifactorial intervention	Intervention with multiple components aiming to assess and address the risk factors and respond to the needs of an individual, usually based on comprehensive assessment (Beswick et al. 2008).	Rehabilitation and management of various dimensions of functioning, exercise; Enhancing home safety; Nutrition support; Management and care of diseases; Medication review; Caregiver support	Semistructured interviews (Kvale et al. 2007) Interviews, focus groups, log books, field notes, documents, photos, video, audio

Table 1. Continued…

Term	Definition	Examples of dimensions	Example(s) of means and measures used in literature
Frailty	Clinical syndrome associated with increased risk of poor health outcomes (Fried et al. 2001). Suggested defining characteristics in addition to poor prognosis are decreased body reserves and decreased ability to counteract stressors (Strandberg et al. 2007).	Unintentional weight loss, weakness, exhaustion, slow gait speed, low physical activity (Fried et al. 2001, Fried et al. 2004); Motivation, motion, communication, balance, activities of daily living (ADL), nutrition, diseases, social contacts (Mitnitski et al. 2001, Fisher et al. 2005)	Fried Criteria (Fried et al. 2001) Frailty Index (FI) (Mitnitski et al. 2001, Fisher et al. 2005)
Physical functioning	Ability to independently take care of daily self-care, tasks at home and surrounding environment, and to live independently in a community (Laan et al. 2014, Motl et al. 2010)	Activities of daily living (ADL) Instrumental activities of daily living (IADL) Activity limitation	Barthel index (Mahoney et al. 1965) Lawton (Lawton et al. 1969) Katz-6 and Katz-15 (Katz et al. 1963, Laan et al. 2014)
Mobility limitation	Restriction in ability to move freely and easily, for example due to a disability or chronic condition (Wilder 1974).	Walking speed, balance, timed up and go	Short Physical Performance battery (Guralnik et al. 1994)
Self-rated health	Participant's self-reported, subjective impression of general health at present state (Tomioka et al. 2017)	General health, subjective view of health Mental health Physical health	"In general, how would you rate your health?" SF-36 (Ware et al. 1992) VAS (Carlsson 1983)
Well-being	Self-reported physical, mental, social and functional well-being and/or life satisfaction (WHOQOL Group 1998)	Freedom to act, active agency Morale Optimism Life satisfaction	WHO-QOL-BREF scale psychological dimension (WHOQOL Group 1998) Psychological well-being scale (Routasalo et al. 2009)
QOL	An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns on many dimensions (Rapley 2003, WHOQOL Group 1994). (See page 30.)	Physical health, psychological health, level of independence, social relationships, environment, personal values and beliefs (See page 31.)	WHOQOL (Rapley 2003, Skevington et al. 2004, WHOQOL Group 1994) (See page 31.)
HRQoL	Effects of health, functioning, illness and the possible impacts of the treatments on the person's QOL on many dimensions (Cummins 1997). (See page 32.)	Physical, mental, emotional and social functioning (See page 32.)	15D (Sintonen 2001) SF-36 (Ware et al. 1992) EQ-5D (EuroQol Group 1990) (See page 32.)

Abbreviations: CGA = comprehensive geriatric assessment; MNA = Mini Nutritional Assessment; MMSE = Mini Mental State Examination; WHO = World Health Organization; RAI = Resident Assessment Instrument; SF-36 = 36-Item Short Form Health Survey (Ware et al. 1992); VAS = visual analogue scale; QOL = quality of life; HRQoL = health-related quality of life; EQ-5D = EuroQol 5 Dimensions.

2.1.2 *Comprehensive geriatric assessment (CGA)*

CGA is multidimensional, systematic and holistic approach to assessment and care of older people, many of whom are multimorbid. CGA was originally developed to ensure that the problems experienced by older people requiring hospital-level care are recognized and acted on. Therefore, the effectiveness of CGA has been well explored in hospital settings and less among home-dwelling older people (Ellis et al. 2017, Lundqvist et al. 2018).

The definition of CGA differs somewhat across applications. In a recent review it was stated that the most commonly used definition for CGA in the literature was: "a multidimensional, multidisciplinary process which identifies medical, social and functional needs, and the development of an integrated / co-ordinated care plan to meet those needs" (Parker et al. 2018). General components used in most CGA programmes include multidisciplinary teams with specialty knowledge, use of standardized instruments to assess older person's medical, physical, cognitive, mental and social functioning and limitations, nutritional status, tailoring treatment plans according to the findings, clinical leadership and multi-disciplinary team meetings (Ellis et al. 2017, Lundqvist et al. 2018). CGA is focused on older person's resources. Table 2 describes the dimensions included in CGA in various studies.

CGA is commonly used in geriatrics. It is currently seen as the quality standard for identifying geriatric syndromes and treating multimorbid older people (Rikkert 2018). CGA is widely used in geriatric hospital settings, especially in geriatric wards but increasingly in all geriatric medicine. In reviews of the literature, the main target group for CGA has been older hospital patients with acute illnesses (Parker et al. 2018). Furthermore, CGA is used in assessment of older people, for example in oncology and pre- and perioperative care of older surgical patients, as it can detect risks that are not usually identified in routine care (Dhesi et al. 2018, Fülöp et al. 2018). There is less literature and experience on CGA in outpatient settings and primary care. CGA has been used, for example, in memory clinics, post-hospitalization follow-ups and PHV interventions (Ellis et al. 2017, Lundqvist et al. 2018, Parker et al. 2018, Stuck et al. 2002). CGA is useful and widely used in long-term care of older patients (e.g. nursing homes). Systematic measures for a structured, reproducible and objective process, for example the Resident Assessment Instrument (RAI) process, have been developed in long-term care (Pitkala et al. 2018a). The literature suggests that CGA should be standardized across healthcare settings to promote better health system coordination and integration (Panza et al. 2018).

Implementing CGA to evaluate and extensively improve older patients' functional, medical, psychosocial and environmental issues has been successful when assessing and treating older populations with multiple health problems and challenges in their everyday lives (Liggins et al. 2010, Lundqvist et al. 2018, Stuck et al. 2002). CGA has a high prognostic value and can be used to predict life expectancy, thus making it a useful tool when making treatment decisions (Dhesi et al. 2018). In earlier research CGA has shown the potential to improve clinical outcomes while reducing health- and social-care costs (Rubenstein et al. 1991). A Cochrane review on the effectiveness of CGA in a hospital setting showed that older people who received CGA were more likely to be living at home and less likely to be institutionalized up to 12 months after hospital admission compared with regular hospital care (Ellis et al. 2017). The results of a recent trial concerning CGA in an outpatient setting suggested that CGA might reduce mortality and increase quality-adjusted life-years (Ekdahl et al. 2016). In the same trial it was suggested that intervention was cost-effective (Lundqvist et al. 2018). However, the total health-care costs increased, partly because of the intervention costs but also because of increased survival leading to patients consuming healthcare resources for a longer time (Lundqvist et al. 2018). Reviews on CGA suggest that its implementation does not increase the total costs of care (Wieland 2003, Ellis et al. 2017).

The shortage of a knowledgeable and skilled work force is a challenge in including CGA in the care processes of older people. Geriatrics is still a minor specialty and unpopular among specialising physicians in many countries (Pitkala et al. 2018c). Therefore, there is lack of trained geriatricians and other trained workforce personnel in geriatrics. Overall, attitudes towards older people's care and a general lack of geriatric knowledge impede the development of geriatric care and implementation of effective geriatric service models (Pitkala et al. 2018a, Pitkala et al. 2018c). CGA has been studied little in outpatient settings. There is no clear conclusion concerning the effectiveness of CGA in outpatient settings and how it should be implemented (Lundqvist et al. 2018). The limited number of geriatricians and skilled geriatric workforce personnel limits the use of CGA in community care and long-term care facilities (Pitkala et al. 2018a). Also, there is still a lack of cost-effectiveness research on CGA. The long-term impact on health outcomes such as quality-adjusted life-years (QALYs) and cost-effects of CGA in the total costs of care should be further assessed (Lundqvist et al. 2018).

Table 2. Dimensions of comprehensive geriatric assessment (CGA) modified from the Oxford textbook of Geriatric Medicine and a Cochrane review (Morris et al. 1999; Pitkala et al. 2018a, Ellis et al. 2017).

Dimension	Examples of assessment instruments	Examples of interventions
Older person's own values and aims		
Older person's own concerns and wishes concerning health	Careful listening of older person and empowering him/her	Focusing on older person's own aims in care
Resources, life story and values	Careful listening of older person and empowering him/her. Summary of the positive findings of CGA	Optimistic and resource-oriented care
Coping	Adjustment to life events, losses, diseases; coping in own home environment; COPE (Juntunen et al. 2017)	Enhancing coping, support in problem solving and active (e.g. exercise, social interaction) and adaptive (e.g. acceptance, hope) coping strategies (Duner et al. 2005)
Medical issues		
Acute problem or disease (in hospital setting)	N.A.	Care of acute symptoms and disease, rehabilitation (Pitkala et al. 2018a)
Comorbidities	Number of diagnoses; Charlson comorbidity index (Charlson et al. 1987)	Choosing care using comprehensive evaluation of benefits and harms of treatments
Other symptoms, latent symptoms	Visual analogue scale for pain (Carlsson 1983); constipation, appetite, sleep	According to aetiology
Risk factors of chronic diseases	Blood pressure, cholesterol, glucose, smoking, alcohol, sedentary lifestyle	According to evaluation of benefits and harms of treatments
Health promotion to prevent geriatric syndromes and complications	Assessing the magnitude of risks of cognitive decline, delirium, immobility, falls, cardiovascular events, depression, etc.	According to evaluation of benefits and harms of treatments
Medication, polypharmacy	Beers' criteria (American Geriatrics Society 2012), STOPP-START criteria (O'Mahony et al. 2015)	Medication review, weighting benefits and harms; recommendations, education of patients and healthcare professionals (Cooper et al. 2015)
Physical and nutritional status	Physical examination, Mini-Nutritional Status (MNA) (Guigoz et al. 2002), height and weight, weight loss	According to findings and aetiology, benefits and harms of treatments; education of patients and caregivers
Functioning		
Functioning in basic activities of daily living (ADL)	Katz (ADL) (Katz et al. 1963), Barthel (Mahoney et al. 1965)	Tailored rehabilitation
Functioning in instrumental activities of daily living (IADL)	Lawton (IADL) (Lawton et al. 1969)	Tailored rehabilitation
Balance, falls	Falls Risk for Older People (FROP) (Russell et al. 2008)	Falls prevention, medication review, exercise programmes (Corrieri et al. 2011, Pitkala et al. 2013, Pitkala et al. 2014)
Mobility	Short Physical Performance Battery, walking speed (Guralnik et al. 1995)	Exercise
Frailty	Fried criteria (Fried et al. 2001)	Exercise, nutrition

Table 2. Continued….

Dimension	Examples of assessment instruments	Examples of interventions
Cognition, cognitive decline	Mini-mental State Examination (MMSE) (Folstein et al. 1975), CERAD protocol (Mirra et al. 1991)	According to aetiology
Mood, depression	Geriatric Depression Scale GDS-15 (de Craen et al. 2003)	According to aetiology, benefits and harms of treatment
Social well-being, loneliness, social isolation, social activity	"Do you suffer from loneliness?" (Routasalo et al. 2009), no. of contacts, no. of hobbies or social activities	Group intervention to empower older people (Pitkala et al. 2009)
Environment		
Home and living environment	Home visit	Home modifications
Social network and support	Inviting relatives/caregivers and people involved in care to care planning	Agreement on care arrangements
Caregivers' / relatives' burden and coping	Zarit Burden Scale (Zarit et al. 1986)	Caregiver education (Brodaty et al. 2012), self-management training (Laakkonen et al. 2016)
Assistive devices	Home visit, assessment of need of aids, assessment of functioning in living environment	Assessment, adjustment and delivery of assistive devices, education on the use of assistive devices
Service needs, economic support	Home visit, service needs assessment	Agreement on care and service arrangements

Abbreviations: COPE = Carers of Older People in Europe; N.A. = not applicable; STOPP-START = screening tool of older people's prescriptions (STOPP) and screening tool to alert to right treatment (START); CERAD = The consortium to establish a register for Alzheimer's disease

2.1.3 *Multiprofessional interventions in prevention*

Multiprofessional teams working in health- and social care are multiform and complex. Several terms and definitions are used in the literature exploring multiprofessional programmes. The World Health Organization (WHO) defined multiprofessional education as "the process by which a group of students (or workers) from the health-related occupations with different educational backgrounds learn together during certain periods of their education, with interaction as an important goal, to collaborate in providing promotive, preventive, curative, rehabilitative and other health-related services" (WHO 1988). The terms and definitions of collaboration of professionals and disciplines in healthcare have been refined over time. The WHO defined *collaborative practice* as a broad term covering teamwork of health workers of different professional backgrounds providing comprehensive services. Collaborative practice in healthcare means multiple health workers from different professions and disciplines co-operating in different areas of health-related work (e.g. prevention, diagnosis, treatment, management) with each other and patients, their families, carers and communities for the highest quality of care (Gilbert et al. 2010).

Multidisciplinary, interdisciplinary and *interprofessional* are commonly used as synonyms for multiprofessional, although they have their own definitions. A profession can be defined as a group of people sharing a common body of knowledge and training under a specific professional name (e.g. Occupational Therapist), whereas discipline means an academic discipline (e.g. sociology) and subspecialties within professions (e.g. geriatrics within healthcare sciences). In a *multidisciplinary team* the professionals work side by side, contributing their disciplines' expertise to the team, whereas members of an *interdisciplinary team* work closely together towards a common goal and communicate actively with each other to improve the quality of care (Hammick et al. 2009). Therefore, *interdisciplinary teamwork* has been suggested to replace the term *multidisciplinary teamwork* (Hammick et al. 2009). However, those involved in PHVs have mainly used the term *multiprofessional team*, and it is difficult to define which team model the studies are actually using.

Webster (2002) also clarifies the terms concerning *multiprofessional teamwork*, considering care of older people, and defining multidisciplinary, interdisciplinary and transdisciplinary teamwork in multiprofessional teams. He remarks that these are actually more specific models of multiprofessional working, whereas *multiprofessional* is more an umbrella term covering several different methods. In a multidisciplinary team each professional works in a team towards their discipline-related goals, whereas an interdisciplinary team takes on a more client-oriented common

goal striving towards overall coordination of goals. Multiprofessional working may be organized in various ways, but overall the goal is to share a common focus, and the older person and his or her family and surroundings should be at the centre of the professionals' efforts and therapeutic activity (Webster 2002). A multiprofessional approach is used in many areas of older people's care in primary care and geriatrics, with various models and intensities. However, most research reports do not describe whether their use of teamwork is in accordance with multidisciplinary or interdisciplinary teamwork. Therefore, in this report the author's original word is used.

The WHO has emphasized the importance of interprofessional and interdisciplinary learning and collaborative practice to improve health outcomes and strengthen health systems (Gilbert et al. 2010). Most research on multiprofessional teamwork in geriatric care concerns hospital settings, for example acute geriatric wards, geriatric rehabilitation wards, consulting geriatric teams and geriatric outpatient clinics (Stuck et al. 1993, Ellis et al. 2017, Pitkala et al. 2018a). In primary healthcare multiprofessional interventions have been used, for example in PHVs, falls prevention, polypharmacy interventions and service needs assessment (Stuck et al. 2002, Mayo-Wilson et al. 2014, Mallet et al. 2007, Baxter et al. 2009). Some community-care services provide multiprofessional, patient-centred models of care, but in many settings older people are still offered traditional, task-based home nursing (Beswick et al. 2008).

Earlier research shows the importance of multiprofessional processes when assessing older people (Liggins et al. 2010). Multiprofessional assessment combined with an individually tailored treatment plan has been identified to promote functional activity, well-being and life satisfaction (Johansson et al. 2009). Multiprofessional and multifactorial programmes with individualized assessment and interventions have been promising features in studies concerning prevention of disability in frail community-dwelling older people (Daniels et al. 2008). In community services involving older people, patient-centred models of care, including multiprofessional interventions, have shown effectiveness (Beswick et al. 2008). Based on earlier systematic reviews, recommendations suggest that employment of a multidisciplinary team is beneficial as a means to assess and meet the complex care needs of for older people, many of whom are multimorbid and have several challenges in their daily lives (Leichsenring 2012, Liggins et al. 2010, Johansson et al. 2009).

When assessing older people, it is important to include primary, secondary and tertiary prevention in the programme, as any one person may have problems at several levels (Mayo-Wilson et al. 2014). The effectiveness of programmes based on multiprofessional assessment and interventions

have been shown to be successful in many areas of prevention concerning older people, for example fall prevention and managing drug interactions (Mallet et al. 2007, Baxter et al. 2009). To be successful, it has been argued that preventive assessment and recommendations have to be tempered by a holistic, multiprofessional team-based approach and include an individualized care plan (Mallet et al. 2007, Ellis et al. 2017, Lundqvist et al. 2018).

Interdisciplinary teamwork has shown effectiveness in assessment and treatment of older people (Gilbert et al. 2010, Johansson et al. 2009, Pitkala et al. 2018a, Stuck et al. 1993). However, compared with a multidisciplinary approach interdisciplinary teamwork is not yet as widely in use owing to a lack of knowledge, skills and education. Varied terms and definitions and their varied use in the literature makes evaluation and research of multiprofessional health work challenging (Beswick et al. 2008, Hammick et al. 2009). Most health workers currently working in the field have not received interprofessional and interdisciplinary education. Furthermore, the structures of health and social care in many settings do not yet support interdisciplinary teamwork, and management might not have the skills to utilise interprofessional and interdisciplinary teams (Gilbert et al. 2010). Thus, a multiprofessional or multidisciplinary approach is more common than an interdisciplinary one. Although shown to be effective in PHV studies a multiprofessional approach might not prove as effective as interdisciplinary working, as the professionals involved work in parallel and not together towards the same goal (Mallet et al. 2007, Ellis et al. 2017).

2.1.4 *Economic analysis of healthcare interventions*

Evaluating the cost-effectiveness of healthcare interventions is important for comparing interventions and their effects and costs. It is also crucial for decision making as both the effectiveness and the costs of interventions affect decisions on new public health programmes (Smith et al. 2015). Several methods of economic analyses are used in studies on healthcare interventions. In this chapter the focus is on the terms and methods used in the context of this dissertation.

Cost-effectiveness analysis compares the costs of new intervention with present care concerning the effects on some outcome, e.g. death, whereas cost-utility analysis compares the costs of different interventions to units which relate to person's well being. Quality-adjusted life-year (QALY) is a commonly used measure for such units. QALY is a composite indicator which allows combining quantity and quality of life on a single index (Smith et al. 2015). It is calculated by weighting each life year to reflect the QOL in that year, either as an area under the curve calculation or as a square root of (length of life^2 + quality of life^2) (Robinson 1993, Smith et al. 2015). The QOL for

calculating QALY is expressed on a numerical scale from 0 to 1, and HRQoL measures which give a single index score on this scale (e.g. EQ-5D, 15D) are commonly used for this. One year lived in perfect health is one QALY, whereas a year lived in less than perfect health is worth less (Prieto et al. 2003).

Incremental cost-effectiveness ratio (ICER) is a way of summarizing cost-effectiveness results of a study. It expresses a ratio of two differences in costs and in effects of the interventions which are being compared. The result indicates the cost of the additional effects of the new intervention. If difference in effects are large enough and/or the relative costs are low enough, the new intervention is considered cost-effective when compared to the current intervention (Smith et al. 2015). The ICER comparisons can be presented as a two-dimensional plot, commonly referred to as the cost-effectiveness plane (Cohen et al. 2008).

Calculation and interpretation of confidence intervals on cost-effectiveness ratios are complicated, thus, one way of managing the uncertainty around point-estimates of ICERs is to use bootstrap resampling where several (e.g. 1000) datasets of the same size as the original are created by resampling from the original data. When the results of these bootstrap iterations are plotted on the cost-effectiveness plane, the results appear as a cloud of possible outcomes. This represents the variability in the original study sample. Then the could can be analysed in different ways, including calculating proportions of the points of the cloud falling on different quadrants of the plane, which describe if the intervention is more or less costly and more or less effective (Cohen et al. 2008).

2.2 Health-related quality of life

2.2.1 *Definition of quality of life (QOL)*

Quality of life (QOL) research is vast. There is no single agreed definition or standard of measurement for QOL. In 1997 over 100 different instruments for measuring QOL were identified (Cummins 1997). The WHO defines the quality of life as: “An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad-ranging concept affected in a complex way by the person’s physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment” (WHOQOL Group 1994). Usually QOL is defined as being multidimensional, with both objective and subjective dimensions. It contains several domains such as material well-being, health, productivity, intimacy, safety, place in community, and emotional well-being (Cummins 1997). The WHO incorporates six domains in their definition: physical health, psychological health, level of independence, social relationships, environment, and personal values and beliefs (Rapley 2003, WHOQOL Group 1994). Table 3 describes the dimensions of QOL.

Table 3. The dimensions of QOL according to various researchers in the field.

Measure/ Dimension	Lawton 1975, 1991	Cummins 1997	Felce & Perry 1997	WHOQOL (Rapley 2003, Skevington et al. 2004)	Vaarama 2009
Health and physical well-being	Health Subjective health Functional health Cognition Health behaviour	Health Disabilities Subjective physical well-being Medication Sense of control Sleep	Objective physical well-being Satisfaction with (subjective) physical well-being Importance of physical well-being	Activities of daily living Dependence on medicinal substances and medical aids Energy and fatigue Mobility, pain and discomfort Sleep and rest	Mobility Subjective health Functional abilities Sense of control Need of help in ADL-activities Acute illness, disability
Environment and material well-being	Environment Safety The level of living	Material well-being The level of living Income Safety	Objective material well-being Satisfaction with (subjective) material well-being Importance of material well-being	Financial resources Freedom, safety and security Health and social care: accessibility and quality Home environment Physical environment Transport	Economic resources, sufficient income Satisfaction with help and services received Safety and comfort Home and living environment and resources Loss of income or home
Psychological and emotional well-being	Mental well-being Mood Psychological symptoms	Emotional well-being Mood Anxiety	Objective emotional well-being Satisfaction with (subjective) emotional well-being Importance of emotional well-being	Bodily image, appearance Negative /Positive feelings Self-esteem Spirituality / Religion / Personal beliefs Thinking, learning, memory and concentration	Mental health Emotional feelings Psychological well-being Emotional support Attitude towards ageing Emotional stress, sorrow
Social relationships and well-being	Social behaviour Interaction Social activities Time use	Place in community Responsibility Social relations Social activities Intimacy	Objective social well-being Satisfaction with (subjective) social well-being Importance of social well-being	Personal relationships Social support Sexual activity	Life satisfaction Social identity and relations Social support Loss of social relationships
Productivity and level of independence		Productivity Leisure activities	Objective development and activity Satisfaction with (subjective) development and activity Importance of development and activity	Work capacity Opportunities for acquiring new information and skills Recreation / leisure activities	Sense of control Education

2.2.2 *Definition of health-related quality of life (HRQoL)*

While quality of life is a broad concept covering all aspects of life, HRQoL is focused on the consequences of health status on QOL. It concerns the effects of health, functioning, illness and the possible impacts of treatments on a person's QOL. Although sometimes used as substitutable terms in the literature, both QOL and HRQoL have their own meanings and nuances (Calman 1984, Cummins 1997). Often HRQoL is illness- or disability-centred, and it may be focused more on physical functioning than overall QOL (Cummins 1997). Well-being is also a concept related to health and QOL. When measuring well-being, the positive aspects of a person's life, such as life satisfaction and positive emotions, are typically assessed (Healthy People 2010, Vaarama 2009). Older people have been observed to score better in positive areas of QOL, i.e. well-being, than younger people (Frytak 2000, Vaarama 2009). Table 4 describes the dimensions of HRQoL in commonly used measures.

Table 4. The dimensions of HRQoL in three commonly used measures.

Measure / Dimension	15D (Sintonen 2001)	SF-36 (Ware et al. 1992)	EQ-5D (EuroQol Group 1990)
Health and physical well-being	Mobility Vision Hearing Breathing Sleeping Eating Elimination Discomfort and symptoms Vitality	Physical functioning Role limitations because of physical health problems Bodily pain General health Vitality	Mobility Self-care Pain / Discomfort
Environment and material well-being			
Psychological and emotional well-being	Mental function Depression Distress Vitality	Vitality Role limitations because of personal or emotional problems Mental-health perceptions	Anxiety / Depression
Social relationships and well-being	Sexual activity Speech	Social functioning	
Productivity and level of independence	Usual activities	Physical functioning Role limitations because of physical health problems	Usual activities

Being multidimensional, HRQoL has physical, mental, emotional and social domains (Guyatt et al. 2007, Ferrans 2005). Although biological and physiological variables and their impacts are often assessed when measuring HRQoL, the components it measures are not limited to physical aspects of health. QOL researchers generally agree that QOL does not depend on physical health alone, but that the health status of a person has a pervasive effect that affects all areas of life widely.

Furthermore, many components of HRQoL assessment require a person's own input. HRQoL cannot be measured without considering a person's own experiences (Guyatt et al. 2007). This makes HRQoL an important patient-reported outcome.

For more than twenty years researchers have recognized the importance of directly measuring how people are feeling, how they are able to function in daily activities, and how their illnesses and treatments affect these areas (Guyatt et al. 2007). This has led to an increase in research and use of different patient-reported outcomes, such as HRQoL. A multitude of various measures and scales have been developed to measure HRQoL (Cummins 1997). HRQoL measures used in research or for assessing patients should be valid, reliable and responsive. They should measure what they are intended to consistently and be able to detect changes in QOL (Guyatt et al. 2007).

Many QOL instruments have been developed for selected groups in a population, especially for assessing QOL in connection with various medical conditions or procedures, for example disease-specific, function-specific, and problem-specific instruments, and scales focused on detecting adverse effects. However, specific scales are not suitable for use in general populations. Therefore, generic instruments for assessing QOL and HRQoL have been developed (Guyatt et al. 2007).

Not even generic instruments can be used without considering the type of population. Scales specifically suitable and valid in their target populations are required, for example to assess children, older people or people with cognitive impairment. Generic instruments, on average, are not as good in detecting treatment effects as specific instruments. However, they are targeted to various aspects of HRQoL. Specific instruments are usually more powerful in detecting treatment effects, but they are often too narrow to assess generic HRQoL, and they can sometimes be too narrow to detect unexpected treatment effects (Guyatt et al. 2007). There are both discriminative scales, which are used to distinguish between who has better and who has worse QOL, and evaluative scales, which measure whether people feel better or worse over time. Discriminative scales should be reliable, whereas evaluative scales should be responsive. Different scales and instruments are needed for different situations, and it is important to determine that the instrument is valid in connection with a particular item (Cummins 1997, Guyatt et al. 2007).

2.2.3 *Why should HRQoL be measured?*

Use of patient-reported and patient-important outcomes is aimed at ensuring that we measure the outcomes and aspects of life that patients value (Guyatt et al. 2007). HRQoL is a multidimensional outcome at individual and population health level. It provides broad summary measures of perceived health and supplements more traditional measures such as mortality (Thompson et al.

2012). Using HRQoL as an outcome measure in research ensures that clinicians and patients can assess a treatment or an intervention not only by the effects it has on physiological aspects, but also on the effects it is expected to have on QOL. The expected effects can then be compared with the patient's values and expectations of the treatment (Guyatt et al. 2007).

We can use HRQoL to explore new insights into the relationships it has with risk factors, and HRQoL measurements help in determining the burden of preventable diseases, injuries, and disabilities on a person's daily life (Thompson et al. 2012). HRQoL offers important information on care providers, clinicians, healthcare organizers and policy makers that can be used to screen and monitor patients as regards their well-being, or in auditing healthcare practice. Population surveys on perceived health problems, health-services research or evaluation research can utilize HRQoL measures. HRQoL can also help regulators in their assessments of new technologies and healthcare policies. HRQoL instruments allow comparisons of quantifiable changes in patients' well-being, which help to appraise the value that, for example, new healthcare technologies or guidelines in healthcare might bring, and they are used, among other things, in the realm of economic analysis (Feeny et al. 2013, Rapley 2003, WHOQOL Group 1994).

In previous literature, a significant difference has been noted between self-reported QOL and proxy reports on individuals with disabilities, named *the disability paradox*. Individuals with disabilities have reported having better QOL than in proxy assessment. This may be related to their coping with disability. The *disability paradox* might mirror the way a person has adapted to live with a disability and their living environment. Thus, well-being is not merely the absence of illness or disability. This paradox underlines the importance of self-reporting when measuring HRQoL (Frytak 2000, Noll 2000, Thompson 2012).

The quality-adjusted life-year (QALY) is a measure that is used in an attempt to represent the impact of a therapy on both on the length of life and HRQoL, thus expressing the additional number of years a person lives as a result of an intervention and the quality of those life years. QALY offers a possibility to assess the effects of an intervention and the costs of intervention and treatment, thus making it a tool to incorporate HRQoL in assessment of the cost-effectiveness of an intervention (Feeny et al. 2013, Whitehead et al. 2010).

2.2.4 *HRQoL in older adults*

Research on the QOL of older people has been a rapidly growing area of interest. This reflects the fact that more and more people spend a longer time at this period of life, as demographic changes show (Noll 2004). The quality of additional life years of this growing population has moved to the

centre of interest because of the increase of life expectancy and the increasing number of people living with a chronic disease (Thompson et al. 2012). Several reports and research initiatives have been targeted at the living conditions and QOL of older adults, and 'old-age surveys' have also been conducted in several countries, such as Sweden and Germany, in recent years (Noll 2004). In research targeted to older people the reduction of morbidity, and not only postponed mortality, is a centre of interest, and HRQoL provides good measurements for this purpose (Allen et al. 2017, Chatterji et al. 2015).

As more than half of older adults have been estimated to have some sort of disability, it is important to look into how disabilities affect their QOL. Therefore, HRQoL is seen as an important tool in assessing older people both as individuals and as a group. Research suggests that higher age, higher medical-care costs, reduced leisure-time physical activity, and smoking are associated with lower QOL among those with functional limitations (Thompson et al. 2012). Although studies suggest that subjective QOL tends to be relatively stable over the different age groups, after the age of 80 years the physical and social dimensions of QOL tend to decline. Thus, the relative importance of the psychological dimension is assumed to increase with age along with losses in other dimensions (Vaarama 2009).

When assessing the QOL of older adults, it is important to consider a possible *response shift*, closely resembling the *disability paradox*. The results of some studies suggest that older people perceive their QOL to be better than among younger people with similar disabilities. One reason behind this might be that as people age, they start to view their health more in relation to their own age, comparing their well-being with that in people of similar age, and can accept that limitations connected with their disabilities have less impact on their overall QOL (Frytak 2000, Thompson et al. 2012). Thus, disability does not automatically mean a lower QOL, and research on what items support the quality of life in this group of the population is important (Frytak 2000, Thompson et al. 2012).

Functioning in activities of daily living (ADL) has been found to have a strong association with all QOL dimensions in older people (Baernholdt et al. 2012, Thompson et al. 2012). Furthermore, cognitive problems, depression and a number of chronic conditions have been found to be associated with the QOL of older people. Thus, early diagnosis and treatment of reduced ADL function, disabilities, cognitive problems and depression are important in improving older adults' QOL (Baernholdt et al. 2012). Interventions aimed at increasing physical activity among older persons with disabilities might help in supporting their QOL (Thompson et al. 2012). Health-

promotion interventions, e.g. PHVs, implementation of CGA and sufficient support and follow-up might offer effective means for supporting older people's functioning and QOL (Stuck et al. 2002).

2.3 Effectiveness of PHVs in older adults

2.3.1 *Effectiveness of PHVs on functioning*

It has been suggested that preventive interventions targeted to older people, including PHVs, could prevent, postpone or slow down functional impairment, leading to a decrease in subsequent undesirable outcomes such as institutionalization (Stuck et al. 2002). Thus, PHV interventions that target functional abilities have been widely studied for decades. During the last decade, frailty and prevention of frailty has become one focus in PHV studies. Frailty is a syndrome associated with adverse health outcomes, often leading to an increase in hospitalization and institutionalization (Fried et al. 2001, Fairhall et al. 2015). Frailty is characterized by loss of physiological reserve capacity and function, increased susceptibility to acute illness, falls, disability, institutionalization, and death (Fried et al. 2001, Behm et al. 2016).

Earlier studies on PHVs were mainly focused on improving or maintaining functioning (Vetter et al. 1984). Home visits were considered important for older people, as they often reported symptoms too late, and disabilities could create difficulties in travelling to a doctor's practice (Vetter et al. 1984). It was also hypothesized that relieving unmet health and social needs and supporting functional ability of older people would decrease the rates of hospitalization and institutionalization (Sorensen et al. 1988). Since the 1980s to the present, PHVs have been widely explored for their effects on functioning, including ADL, instrumental activities of daily living (IADL), and deficits of functioning and their prevention. Most investigators have reported the outcomes of functioning as estimates of the effects on overall functioning, i.e. ADL and IADL (Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, Fabacher et al. 1994, Granbom et al. 2017, Imhof et al. 2012, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Stuck et al. 1995, Stuck et al. 2000), but some have reported only some aspects of functioning, for example the number of people dependent in connection with specific activities (e.g. eating, personal hygiene) (Gustafsson et al. 2012, Sorensen et al.1988, Schraeder et al. 2001, Mayo-Wilson et al. 2014).

The characteristics of the 33 studies included in the literature review are described in Table 5.

Measures

Functioning has been defined and measured in a variety of ways in PHV studies. Most commonly functioning is defined by independence or dependence in connection with basic activities of daily living (ADL) and instrumental activities of daily living (IADL). It is commonly measured on the Barthel scale (ADL) (Mahoney et al. 1965, Brettschneider et al. 2015, Kono et al. 2016), Katz-6 (ADL) and Katz-15 indices (ADL and IADL) (Katz et al. 1963, Laan et al. 2014, Bleijenberg et al. 2016, Fabacher et al. 1994, Granbom et al. 2017), the Groningen Activity Restriction Scale (GARS) (ADL and IADL) (Kempen et al. 1996, Bouman et al. 2008a, Melis et al. 2008, Metzelthin et al. 2015), the Lawton scale (IADL) (Lawton et al. 1969, Stuck et al. 1995, Brettschneider et al. 2015, Fabacher et al. 1994) and the Older Americans Resources and Services scale (OARS) (ADL and IADL) (Fillenbaum et al. 1981, Imhof et al. 2012, Ploeg et al. 2010), although other measures have also been used.

In some studies lists of items related to functioning and daily activities have been used to measure functional ability. These items include, for example, the number of restricted activity days in bed (Schraeder et al. 2001), difficulty in walking (Gustafsson et al. 2012, Schraeder et al. 2001), urinary or faecal incontinence (Schraeder et al. 2001, Sorensen et al. 1988), dressing, cooking (Gustafsson et al. 2012, Sorensen et al. 1988), vision (Schraeder et al. 2001, Sorensen et al. 1988), hearing (Sorensen et al. 1988), cleaning, shopping, transportation, bathing, going to the toilet, and feeding (Gustafsson et al. 2012).

Many of the more recent studies have been focused on the effects of PHVs on prevention of frailty or enhancing the functional abilities of frail older people (Behm et al. 2016, Bleijenberg et al. 2016, Fairhall et al. 2015, Granbom et al. 2017, Gustafsson et al. 2012, Kono et al. 2012, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015). Some PHV studies have concerned the effects of preventive and health-promoting interventions in postponing deterioration in frailty (Behm et al. 2016) and reducing the degree of frailty (Bleijenberg et al. 2016, Granbom et al. 2017, Fairhall et al. 2015). The definition of frailty has varied in these studies. Most studies focusing on frail participants or on prevention of frailty have involved the use of Fried criteria (Fried et al. 2001), or a modified version of them (Behm et al. 2016, Gustafsson et al. 2012, Fairhall et al. 2015), or the Groningen Frailty Indicator (GFI) (Steverink et al. 2001, Melis et al. 2008, Metzelthin et al. 2015).

Table 5. Randomized controlled trials (RCTs) concerning the effects of preventive home visits (PHVs) on older peoples' 1) health-related quality of life (HRQoL), well-being, 2) functioning, 3) use and costs of healthcare and social services, and 4) mortality.

Study / Country Sample size (no. IG/CG)	Characteristics of participants	Intervention	Visits / duration of intervention Interventionists	Outcomes	Quality[1]
Behm et al. 2016 Sweden N=459 (174/171/114)	80y+ (median 86y), 63% females, 13% were nonfrail, 68% prefrail, and 19% frail. Inclusion criteria: living in their ordinary housing, no home help service or care arranged by the urban districts, independent of help from another person in ADL, and MMSE ≥ 25	Two intervention arms: 1. A single home visit guided by a protocol made by a professional; verbal and written information and advice; falls risk assessment; duration 1.5–2 hours. 2. Multiprofessional senior group meetings (4 meetings), one follow-up home visit	1 per year / 12 months 1. Nurse, occupational therapist or physiotherapist, or social worker 2. Multiprofes-sional team	2) Mob-T Scale. Sum of eight frailty indicators: In both intervention groups the risk of becoming increasingly frail measured as tiredness in ADL was significantly lower at the 1-year follow-up vs. the control group. No significant difference between groups concerning deterioration in the number of frailty indicators. At the 2-year follow-up, there were no significant differences between the groups.	High 9/10
Bleijenberg et al. 2016 Netherlands N=3092 (790/1446/856)	60y+ (mean 74y), 57% females, 29% living alone. ≥ 1 criteria: Multimorbidity (frailty index score ≥ 0.20), Polypharmacy (≥ 5 different medications), ≥ 3-year care gap in primary care; Excluded: terminally ill, estimated life expectancy of ≤ 3 months, living in assisted-living or nursing home	Two intervention arms: 1. Screening (n=790): Screened for multimorbidity and polypharmacy, quarterly reports to GPs, GPs advised to act upon these reports according to the current guidelines 2. Screening + nurse-led care (n=1446): CGA at home, additional visits based on needs, individualized intervention	1. none 2. 1+ per year / 12 months Nurse	1) EQ-5D, self-reported QOL, SF-36 and satisfaction with care: no significant differences between the three groups 2) Katz-15: Participants in both of the IGs had less decline in ADLs vs. the CG (12-month follow-up). 3) Number of hospital admissions, number of ED visits: no significant differences between the three groups 4) No significant difference between the three groups in mortality.	High 8/10
Bouman et al. 2008a Netherlands N=330 (160/170)	70-84y (mean 76 y), 60% females. 35% lived alone. Home-dwelling. Excluded: SRH moderate to good, regular home nursing care, or in waiting list for a nursing home.	Home visits 8× / 18 months; Phone contact possibility in between visits.	8 per year / 18 months Home nurse with specific training	1) SF-20: No significant differences between groups in QOL. 2) ADL, IADL (GARS): No significant differences between groups in functioning on ADL and IADL measures used.	High 9/10
Brettschneider et al. 2015 Germany N=305 (150/155)	80y+ (mean 85y), 69% females. 65% living alone. Home-dwelling or discharge from hospital to home planned. Excluded: not speaking German, cognitive impairment, care level over 1.	Multidimensional geriatric assessment; multiprofessional team consultation in 3 weeks; 2 booster visits during circa 2-3 months from the assessment visit; follow up 18 months	3 per year / 3 months trained personnel: nursing scientist / psychologist / sociologist	1) EQ-5D, and 2) Barthel (ADL), Lawton (IADL): No significant differences between groups. 3) No significant differences between groups in hospital and nursing home admissions, nursing visits, informal care and outpatient physician services. 4) Mortality: Lower number of deceased patients in IG.	High 8/10

Table 5. Continued…

Byles et al. 2004 Australia N=1569 (942/627)	70y+, 50% females. Veterans and war widows, living in the community	Four intervention arms: 1. annual visits with a report to GP and telephone follow-up after visit 2. as 1 with additional report to GP after telephone follow-up 3. as 1 but 6-monthly visits 4. as 3 with additional report to GP after telephone follow-up	1-2 per year / 36 months Nurse, social worker, psychologist, physiotherapist or occupational therapist	1) SF-36: IGs reported significantly higher QOL on subscales of physical functioning, general health, vitality and social functioning at 3-year follow-up vs. CG. 3) IG participants were significantly more often recorded as having been admitted to nursing home than CG, no significant difference in hospital admissions between groups. 4) No significant difference in mortality between groups.	High 10/10
Crawford Shearer et al. 2010 USA N=59 (32/27)	60y+ (mean 78 y), 71% females. Meals-on-wheels through the local Community Action Agency, English-speaking, able to hear, and had sufficient cognitive capacity to respond to surveys and give informed consent.	Standardized weekly home visits for six consecutive weeks.	6 per year / 3 months Nurse	1) GAS: A significant increase in purposeful participation in goal attainment measured using the GAS in IG vs. CG. Ryff's Psychological Scale and Barrett's PKPCT total score or for WPS: no significant difference between groups.	High 10/10
Dalby et al.2000 Ontario, Canada N=142 (73/69)	70y+ (mean 79y), 67% females. 39% were living alone. Included: Reported functional impairment or admission to hospital in the previous 6 months. Excluded: living in nursing home, previous home visits	Comprehensive assessment; follow-up visits as needed for 14 months. Phone contact possibility in between visits	varied / 14 months Nurse with training in gerontology	3) No significant difference in health services utilization between groups, except influenza and pneumonia vaccination rates were higher in the IG. 4) No significant difference in mortality between groups.	Moderate 5/10
McEvan et al. 1990 England N=296 (151/145)	75y+ Persons registered with the practice taking part in the study in 1986. Excluded if in hospital care.	Home visit with structured assessment (incl. blood pressure, urinalysis, haemoglobin level and compliance with medication); advice about problems identified and heating the home; information booklet was given; additional visits at 7 months and 20 months	1-2 per year / 20 months Nurse	1) Morale was significantly better in the IG with respect to attitude to own ageing and loneliness at follow- up. IG had significantly better emotional reaction score at follow-up. IG had significantly better isolation scores than CG at baseline and follow-up. 2) and 3) No significant differences were found in ADL or in use of health and social services between the groups. 4) No significant difference between groups in mortality.	Moderate 7/10
Fabacher et al. 1994 Los Angeles, USA N=254 (131/123)	70y+ (mean 72y), 2% females, 20% living alone. Community-living veterans. Excluded if: currently receiving healthcare or suffering from terminal disease or dementia.	Initial in-home assessment, including home safety evaluation, individualized health education; assessment reviewed with geriatrician; follow-up visits at 4-month intervals by volunteers	4 per year / 12 months Nurse or physician's assistant and volunteers	2) Katz-15, Lawton: no significant difference in ADL scores between groups, but CG subjects' IADL scores declined significantly more over the 1-year follow-up vs. IG 3) No significant difference in self-reported fall rates, and rates of hospitalization or institutionalization between groups.	Moderate 5/10

Table 5. Continued…

Study / Country Sample size (no. IG/CG)	Characteristics of participants	Intervention	Visits / duration of intervention Interventionists	Outcomes	Quality[1]
Fairhall et al. 2015 Australia N=241 (120/121)	70y+ (mean 83y), 61% females. 46% lived alone. Those included met CHS criteria for frailty. Excluded: resided in an aged care facility, had severe cognitive impairment, had a life expectancy under 12 months.	Geriatric evaluation and management; individualized intervention; medication review; management of chronic conditions; 10 physiotherapy visits and individualized home programme	10+ per year / 12 months Interdisciplinary team	1) EQ-5D: no significant differences between IG and CG 2) CHS criteria: The prevalence of frailty was significantly lower in the IG at 12 months vs. CG. 3) No differences between groups in hospital admissions or nursing-home admissions. In very frail subgroup the intervention was dominant: both more effective and less costly than control.	High 10/10
Frese et al. 2012 Germany N=1620 (630/990)	70y+ (mean 82y). 71% females, 25% lived alone, 12% had severe dementia	Step assessment and visit 1×/year for 1-2 years (mean 1.3 visits)	1 per year / 24 months Trained medical student	3) IG had a better chance of staying in the community (not dying or being admitted to a nursing home) vs. CG.	Poor 4/10
Granbom et al. 2017 Sweden N=153 (80/73)	65y+ (mean 81y), 67% females, 34% married or living together Home-dwelling, dependent on help in ≥ 2 ADLs, 2+ hospital admissions or 4+ visits to primary care in last 12 months Excluded if: moved to special housing, < 25 on MMSE or could not communicate verbally	Monthly home visits during one year; four parts: traditional case management (e.g. assessment); general information; specific individualized information; safety (phone contact). The content of the intervention was based on these four parts and individualized to the participant's needs and wishes.	12 per year / 12 months Nurse and / or physiotherapist	2) No differences between groups in social participation. IG participants performed leisure activities in general, and important physical leisure activities, to a greater extent than the control group at the 3-month follow-up. Significantly more participants from the IG had an increased or unchanged number of important social leisure activities that they performed for the period from baseline to 3 months vs. CG.	High 9/10
Gunner-Svensson et al. 1984 Denmark N=4128 (2055/2073)	70y+ (46% 80y+, estimated mean 79y), 58% females, 58% were singles. Excluded: had participated in a pilot investigation, were living in a nursing home or deceased	Interview visit, structured interview; individualized care plan made with the participant; follow-up visits of risk-group participants or when intervention was initiated.	1+ per year / 48 months Nurse	3) Nursing home admissions of 80y+ old women were significantly lower in the IG vs. CG. No significant difference in nursing home admissions in men or other age groups. No difference between groups in the average duration of residence in nursing home.	Moderate 5/10

Table 5. Continued…

Gustafsson et al. 2012 Sweden N=459 (174/171/114)	80y+ (median 86y), 63% females, 13% were nonfrail, 68% were prefrail, and 19% were frail Inclusion criteria: living in their homes, no home help or care arranged by the urban districts, independent of help from another person in ADL and MMSE ≥ 25	Two intervention arms: 1. A single structured home visit; verbal and written information and advice; falls risk assessment; duration 1.5-2 hours. 2. 4 weekly, multiprofessional, 2-hour group meetings focused on information and discussion	1. 1 per year / 12 months 2. none / 12 months 1. Nurse, occupa-tional therapist, physiotherapist, or social worker	2) 1. There was a significant difference in favour of IG vs. CG for no deterioration in SRH. No significant difference in frailty between the groups. 2. There was a significant difference between IG and CG for no deterioration in SRH. There was a significant difference in favour of IG vs. CG for no deterioration SRH and in favour of IG2 vs. CG and IG1 in no deterioration in ADLs. No significant difference in frailty between the groups.	High 9/10
Hebert et al. 2001 Quebec, Canada N=503 (250/253)	75y+ (mean 80 y), 64% females. 45% were married. At risk of functional decline (≥ 1 risk factor in Sherbrooke Postal Questionnaire). Spoke French or English.	Assessment by evaluation programme; GP consultation; visit or phone contact 1×/month for one year; phone contact possibility in between visits.	1+ per year / 12 months Trained nurse	1) General Well-Being Schedule, Social Provisions Scale: and 2) SMAF disability scale: No difference between groups in QOL, well-being and functioning. 3) No difference between the groups related to health service utilization. 4) No significant difference between groups in mortality.	Moderate 7/10
Hendriksen et al. 1984 Denmark N=572 (285/287)	75y+ (median 78.5y), 62% females. Living in their homes	Interview visit 4×/year; max 12 visits; structured questionnaire, information; phone contact possibility in between visits	4 per year / 36 months Nurse	3) Significantly fewer hospital admissions, hospital-bed days, lower mortality, fewer emergency medical service calls, more use of social services in IG. No difference in admission to nursing homes or home-nursing care between groups.	Poor 4/10
Imhof et al. 2012 Switzerland N=461 (231/230)	80+ (mean 85y), 73% females, 67% lived alone. German-speaking, community-dwelling, cognitively able to give informed consent. Excluded: at the end of life or with a major psychiatric diagnosis or severe cognitive impairment (on Clinical Dementia Rating Scale).	Complementary 9-month in-home health consultation programme (HCP): Four home visits after 4, 12, 24 and 36 weeks, and three telephone calls after 8, 18 and 30 weeks.	4 per year / 9 months Nurse with specific training	1) WHOQOL-Bref: no significant differences between the groups in QOL in 9-month period. 2) OARS: no significant differences between the groups in ADL in 9-month period. 3) the number of 3-month periods with hospitalization and usage rate of pharmacist consultations were significantly lower in the IG Other: Significant reduction in the number of falls and acute events in the IG during the 9-month period.	High 8/10

Table 5. Continued…

Study / Country Sample size (no. IG/CG)	Characteristics of participants	Intervention	Visits / duration of intervention Interventionists	Outcomes	Quality[1]
Kono et al. 2012, 2013 Japan N=323 (161/162)	65y+ (mean 80y), 74% females. 28% lived alone. Mean Barthel index 91. Living in their homes. Those included were at risk of functional decline: LTCI system support level 1 or 2. Excluded: using formal long-term care	Visit 2×/year for 2 years; structured multidimensional assessment with 5 key elements: locomotion, daily activities, social contacts or relationships with other people, health conditions, signs of abuse; provided recommendations	2 per year / 24 months Community health nurse, care manager or social worker	2012 report: 2) Barthel, Index of Competence: No significant difference in between groups. Functional status and depression were significantly less deteriorated among those in IG who were dependent in ADLs vs. similar CG. 3) No significant differences in institutionalization or hospitalization between the groups; 2013 report: 3) No difference between groups in mean healthcare costs, mean outpatient clinic healthcare costs or hospital care costs.	High 10/10
Kono et al. 2016 Japan N=360 (179/181)	65y+ (mean 79.2y), 75% females half in each support levels 1 and 2	Visits every 3 months based on a systematic structured assessment sheet of care needs, four domains: health, mental health, activities, and participation; comprehensive individualized recommendations	4 per year / 24 months community care nurses, social workers, or care managers	2) Barthel, Index of Competence: ADLs in CG participants were significantly worse over time vs. IG. 3) No significant differences in total costs per person over 36 months between IG and CG. From 7 months to 15 months the IG participants used more long-term care services than CG. 4) No significant difference in mortality between groups.	High 8/10
Melis et al. 2008 Netherlands N=151 (85/66)	70y+ (mean 82y), 75% females. 51% received home care, 53% had ADL dependencies. Home-dwelling or living in a home for the aged. Frail: had problems in cognition, nutrition, behaviour, mood or mobility.	Geriatric assessment; up to 6 visits during 3 months	up to 6 per year / 3 months Geriatric specialist nurse	1) MOS-20MH and 2) GARS: Significantly more people in IG experienced an improvement in well-being without a decline in functional performance vs. CG. 3) For IG hospitalization and institutionalization costs were less, and home care, day care, and meals-on-wheels were more expensive. Treatment reported cost-effective with a willingness to pay 34,000 € per successful treatment.	High 9/10
Metzelthin et al. 2015 Netherlands N=346 (193/153)	70y+ (mean 77y), 58% females. 49% lived alone. Frail: GFI score 5 or higher Mean GFI score 7.0.	Assessment; GP consultation or team meeting; 2nd home visit, individualized treatment plan: toolbox of guidelines; if need for follow-up, 24-month follow-up	2 per year / 6 months Nurse with support team	1) EQ-5D and 2) GARS: no significant differences between the groups 3) No significant differences between groups in hospital use, long-term care, informal care or in-home modifications, or in total costs. IG used more primary care than CG.	High 8/10
Pathy et al. 1992 Wales, Great Britain N=725 (369/356)	65y+ (mean I 69, C 74), 60% females. Living in domestic accommodation. 33% were living alone.	Survey via mail; if problems were detected in survey, home visit was issued; referrals to GP and services	varied per year / 36 months Health visitor	1) IG showed better self-rated health (SRH) than CG. 2) No difference in functioning between groups. 3) IG showed fewer home visits but more visits to the GP. No differences between groups in hospital admissions or admissions to long-term care. 4) Lower mortality in IG vs. CG.	Poor 4/10

Table 5. Continued…

Ploeg et al. 2010 Ontario, Canada N=719 (361/358)	75y+ (mean 81y), 53% females, 34% lived alone. Persons at risk of functional decline (≥ 1 risk factor). Excluded: received home care, lived in an institution, palliative care, scheduled for major elective surgery or planning to leave the country.	Comprehensive assessment; visits (mean 3) during 1 year; information, referrals to healthcare and support services; note-card; physician consultation. Phone contact possibility in between visits.	3 per year / 12 months Nurse	1) Health Utilities Index Mark 3 (Furlong et al. 2001), SRH and 2) OARS: No significant differences between groups. 3) No differences between groups in costs of health and social services, hospital admissions, number of patients admitted to a long-term care home, or costs of prescription drugs. 4) No significant difference in mortality between groups.	High 8/10
Sahlen et al. 2006, 2008 Sweden N=542 (196/346)	75y+ (mean 80 y), 55% females. All living in their homes independently without home help or home-nursing care.	Visits 2×/year for 2 years; visits followed a structured programme and lasted 1.5-3h	2 per year / 24 months Nurse or care manager	2008 Report: 1) IG gained 63 more QALYs vs. CG. 3) IG used significantly less elderly care and received more influenza vaccinations vs. CG. No difference between groups in use of hospital beds. Costs were about 14000 €/QALY gained. 2006 Report: 4) During the intervention mortality was significantly lower in IG vs. CG, but during follow-up the difference between the groups disappeared.	Moderate 6/10
Schraeder et al. 2001 Illinois, USA N=941 (530/411)	65y+ (mean 76y), 73% females, 49% lived alone. Community dwelling. At least one risk factor from a list: hospitalized in 6 months, lived alone, lacked a caregiver, ≥ 4 prescription medications, difficulty in walking, limitations in ADL and/or memory, incontinent (urine or stool), multiple illnesses or disabilities requiring special care.	In-home / at office assessment; visits (mean 7.5) as needed during 2-year follow-up. Phone contact possibility.	4 per year / 24 months Registered nurse	2) At 12 months the IG had significantly lower HSQ scores in mental health and energy/fatigue. At 24 months there were no significant differences between the groups. 3) No differences between groups in hospital admissions, length of stay or Medicare payments. 4) Mortality reduced significantly in IG vs. CG.	Moderate 7/10
Shapiro et al. 2002 Florida, USA N=105 (40/65)	Mean age 77y, 81% females. On waiting list to receive social services classified as "moderate risk" and could self-report.	In-home geriatric assessment; individualized services; contact every 3 months at the minimum; several services were provided according to individual needs	4+ per year / 18 months Nurse and case manager	1) The depression score decreased and satisfaction with social relationships, mastery, and life satisfaction increased significantly in the IG vs. CG. 3) IG participants were significantly less likely to be institutionalized or to die than those in CG.	Moderate 7/10

Table 5. Continued….

Study / Country Sample size (no. IG/CG)	Characteristics of participants	Intervention	Visits / duration of intervention Interventionists	Outcomes	Quality[1]
Sorensen et al.1988 Denmark N=1555 (777/778)	75y+ (mean 80y), 48% females, 41% married. Random sample based on birth dates.	In-home assessment during a 2-hour home visit. If needed, referral to GP.	1 per year / 12 months social worker and physician	1) QOL, loneliness and 2) functioning: No significant difference between the groups. 3) Institutionalization, hospitalization and 4) mortality: No differences between groups.	Poor 2/10
Stuck et al.1995 California, USA N=414 (215/199)	75y+ (mean 81y), 70% females. 64% were living alone, 92% were independent in basic ADL. Home-dwelling. Excluded: severe cognitive or functional impairment, about to move into nursing home, terminal disease, language problems.	Annual geriatric assessment for 3 years; visits 4×/year for 3 years (mean 11 visits); phone contact possibility in between visits	4 per year / 36 months Gerontology nurse	2) ADL, IADL: Significantly less dependence in ADL in IG vs. CG. 3) IG had fewer permanent nursing home admissions but more outpatient visits. No significant differences in hospital admissions, the number of short-term nursing home stays or the use of in-home and supportive services between groups. Cost for each disability-free year of life was approx. $6000, and prevention of a long-term stay day in nursing home $35.	High 9/10
Stuck et al. 2000 Switzerland N=791 (264/527)	75y+ (mean 82y), 74% females, 55% were living alone, 30% were dependent in their IADL. Community-dwelling. Excluded if living in institution, not speaking German, a terminal disease. Predetermined subgroups according to their baseline risk.	Annual geriatric assessment for 3 years; visits 4×/year for 3 years; consultation with geriatrician, recommendations were conducted in in-home visits.	4 per year / 36 months Nurse with training in gerontology	2) ADL, IADL: IG had less dependence in IADL and better gait and balance scores than CG in follow-up. No differences between groups in basic ADL. 3) IG had more influenza vaccinations and visits to primary care than CG. Low baseline risk groups (ZIP A and B). IG had higher healthcare costs in 1st and 2nd year, but in 3rd year prevention of nursing-home admissions resulted in savings. 4) No differences between groups in mortality.	Moderate 7/10
Van Hout et al. 2010 Netherlands N=651 (331/320)	75y+ (mean 81y), 69% females. 55% lived alone, 14% had cognitive impairment. Included: home-dwelling, reported COOP-WONCA worst quartile in ≥ 2 of 6 charts. Excluded: terminally ill, dementia, institutionalized.	RAI-HC assessment; visits up to 4×/year during 18 months (mean 3); individual care plan, GP consultation	up to 4 per year / 18 months Home nurse	1) SF-36: no significant differences between groups 2) COOP-WONCA, GARS: no significant differences between groups 3) No significant differences between groups in hospitalization and institutionalization. The persons in IG with poorest SRH had a significantly higher risk of being admitted to a hospital vs. the CG.	High 9/10
Van Rossum et al. 1993 Netherlands N=580 (292/288)	75-84y (estimated mean 78y), 58% females. 39% were living alone, > 60% had household disabilities. Home-dwelling with no home-nursing care.	Home visits 4×/year for 3 years, extra visits if needed; referrals made to GP and services; phone contact possibility in between visits	4+ per year / 36 months Nurse	1) Well-being, SRH and 2) functional state (5 questions): No significant difference between groups. 3) More hospital admissions in the CG vs. IG, no difference in length of hospital stays, institutionalization or use or costs of services. 4) No significant difference in mortality between groups.	High 9/10

Table 5. Continued….

Vetter et al. 1984 Wales, Great Britain N=1148 (577/571)	70y+ retrieved randomly from two general practices	Interview visit by independent interviewer; home visits 1×/year for two years: information, note-card, follow-up for high-risk patients	1 per year / 24 months Nurse	2) No significant differences between groups in subjective view of life, changes in anxiety score or physical disability. 3) No significant differences between groups in total use of services. In subgroup of Gwent, IG had significantly more home help than CG. 4) In subgroup of Gwent, IG had significantly fewer deaths.	Moderate 6/10
Yamada et al. 2003 Japan N=368 (184/184)	65y+, (mean 79y), 63% females, 9% living alone. Community-dwelling, dependent in IADL and independent in ADL.	Scheduled visits with 3–6-month interval, MDS-HC to assess the elderly person, individualized instructions based on the assessment.	6 per year / 18 months Nurse	1) EQ-5D: no significant differences between groups. Among those who rated their own health as poor at baseline, the EQ-5D score at the end of the trial was better in the IG vs. the CG. Other: More in IG ceased smoking and cared for oral health.	High 9/10

Abbreviations: RCT = randomized controlled trial; PHV = preventive home visit; no. IG/CG = number of participants in intervention /control groups; N = total number of participants; y = years of age; IG = intervention group; CG = control group; HRQoL = health-related quality of life; ADL = activities of daily living; MMSE = mini-mental state examination (Folstein et al. 1975); Mob-T scale = measure of tiredness in daily activities (Schultz-Larsen & Avlund, 2007); GP = general practitioner; CGA = comprehensive geriatric assessment; QOL = quality of life; EQ-5D = EuroQol 5-dimensional measure for HRQoL (EuroQol Group 1990), SF-36 = 36-Item Short Form Health Survey (Ware et al. 1992); Katz-15 = measure of functioning combining Katz-6 and Lawton IADL questionnaires (Laan et al. 2014); IADL = instrumental activities of daily living; Lawton = Lawton IADL questionnaire (Lawton 1991); ED = emergency department; SRH = self-rated health; SF-20 = Medical Outcomes Study 20-item Short Form Survey (Hays et al. 1995); GARS = Groningen Activity Restriction Scale (Kempen et al. 1996); GAS = Goal attainment scale, 5-point scale with ratings based on the achievement of desired goal(s) in a given time frame (Kiresuk & Sherman, 1968); Barret's PKPCT = Power as Knowing Participation in Change Tool, a 48-item semantic differential scale – a higher score indicates a greater degree of purposeful participation (Barrett, 1986); WPS = Well-being Picture Scale, a general index of well-being, containing 10 pairs of bipolar drawings (Gueldner et al., 2005); CHS = Modified Fried frailty criteria, Cardiovascular Health Study frailty criteria (Fried 2001); General Well-Being Schedule = Dubuy's General Well-Being Schedule, 18-item well-being questionnaire covering six dimensions (Dubuy 1978); Social Provisions Scale = 24-item scale exploring six dimensions of perceived social support (Cutrona et al. 1978); SMAF = Functional Autonomy Measurement System, 29-item disability scale measuring functional ability in five areas (Hebert et al. 1988); HCP = health consultation programme; WHQOL-Bref = an abbreviated version of the WHOQOL assessment measure (WHOQOL Group 1994); OARS = Older Americans Resources and Services ADL measure (Fillenbaum et al. 1981); LTCI = long-term care insurance system (Tamiya et al. 2011); Barthel = Measure of ADL functions, scoring of ADLs ranges from 0 to 100 (Mahoney et al. 1965); Index of Competence = Measure of IADLs developed by the Tokyo Metropolitan Institute of Gerontology consisting of 13 items in three subscales: instrumental self-maintenance, intellectual activity, and social role, scored as 1 for 'yes' or 0 for 'no' and high scores indicating relatively high levels of functioning (Koyano et al. 1991); MOS-20MH = mental well-being using the mental health subscale of the Medical Outcomes Study Short Form SF-20 (Hays et al. 1995); GFI = Groningen Frailty Index, range 0–15: higher score indicates more severe frailty (Steverink et al. 2001); QALY = quality-adjusted life-year; HSQ = Health status questionnaire to assess functional status (Barry et al. 2007); ZIP code = a postal code used by postal services; COOP-WONCA = Measure of overall health, physical fitness, changes in health, daily activities, mental health, social activities, scoring range 1 = excellent to 5 = very bad (Nelson et al. 1987); RAI-HC = resident assessment instrument for home care (Morris et al. 1999, Morris et al. 2013); MDS-HC= Minimum Data Set-Home Care 2.0 protocol, using assessment items serving as 'triggers' that lead to a review in 30 domains (Morris et al. 1997).

[1] Quality of a trial is based on the evaluation criteria presented in Table 8.

Characteristics of target groups and interventions

Altogether, 24 studies have been carried out to explore the effects of PHVs on functioning, functional limitations, or frailty (Behm et al. 2016, Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, McEvan et al. 1990, Fabacher et al. 1994, Fairhall et al. 2015, Granbom et al. 2017, Gustafsson et al. 2012, Hebert et al. 2001, Imhof et al. 2012, Kono et al. 2012, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Pathy et al. 1992, Ploeg et al. 2010, Schraeder et al. 2001, Sorensen et al.1988, Stuck et al.1995, Stuck et al. 2000, Van Hout et al. 2010, Van Rossum et al. 1993, Vetter et al. 1984). These studies were performed between 1984 (Vetter et al. 1984) and 2017 (Granbom et al. 2017).

The participants and interventions in PHV studies targeting functioning, deficits of functioning, and frailty have varied in different studies. The mean age of participants in high- and moderate-quality studies has ranged from 72 years to 86 years. This variation can be explained by the range of minimum age in inclusion criteria of the studies, which varies from 60 years and over (Bleijenberg et al. 2016) to 80 years and over (Behm et al. 2016, Brettschneider et al. 2015, Gustafsson et al. 2012, Imhof et al. 2012).

The participants of all studies included were independent community-dwelling older people. Six studies had no other inclusion or exclusion criteria (McEvan et al. 1990, Metzelthin et al. 2015, Pathy et al. 1992, Sorensen et al. 1988, Van Rossum et al. 1993, Vetter et al. 1984). A decline in functioning was included as an inclusion criterion in 11 studies (Bleijenberg et al. 2016, Fairhall et al. 2015, Granbom et al. 2017, Kono et al. 2012, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Van Hout et al. 2010, Hebert et al. 2001, Schraeder et al. 2001). Common exclusion criteria were a severe decline in cognition, included in nine studies (Behm et al. 2016, Brettschneider et al. 2015, Fabacher et al. 1994, Fairhall et al. 2015, Granbom et al. 2017, Gustafsson et al. 2012, Imhof et al. 2012, Stuck et al.1995, Van Hout et al. 2010), and terminal disease, included in eight studies (Bleijenberg et al. 2016, Fabacher et al. 1994, Fairhall et al. 2015, Imhof et al. 2012, Ploeg et al. 2010, Stuck et al.1995, Stuck et al. 2000, Van Hout et al. 2010).

A nurse performed the home visit intervention in most studies (Bleijenberg et al. 2016, Bouman et al. 2008a, McEvan et al. 1990, Fabacher et al. 1994, Granbom et al. 2017, Hebert et al. 2001, Imhof et al. 2012, Kono et al. 2012, Kono et al. 2016, Melis et al. 2008, Pathy et al. 1992, Ploeg et al. 2010, Schraeder et al. 2001, Sorensen et al.1988, Stuck et al.1995, Stuck et al. 2000, Van Hout et al. 2010, Van Rossum et al. 1993, Vetter et al. 1984). However, in five studies multiprofessional home visit intervention was carried out (Behm et al. 2016, Brettschneider et al. 2015, Fairhall et al. 2015,

Gustafsson et al. 2012, Metzelthin et al. 2015). The number of home visits and duration of the intervention varied across the PHV studies targeting functioning. The number of visits ranged from one home visit (Behm et al. 2016, Gustafsson et al. 2012, Vetter et al. 1984) to 12 visits during one year (Granbom et al. 2017). The duration of intervention ranged from three months (Brettschneider et al. 2015, Melis et al. 2008) to 36 months (Stuck et al. 1995, Stuck et al. 2000). When comparing the studies, none of these characteristics appeared to have an apparent relationship to favourable effects of the intervention.

Studies involving comparison of PHVs with other active interventions have not shown superiority in effectiveness (Bleijenberg et al. 2016, Behm et al. 2016). In one study there was a screening intervention (ambulatory care consultation) as a third study arm. Based on this, some of the screened participants also received home visits (Bleijenberg et al. 2016). In this RCT both screening intervention and a preplanned PHV programme showed effectiveness, with participants in both of the intervention groups showing less decline in daily functioning than those in the control group at one-year follow-up (Bleijenberg et al. 2016). A three-arm trial carried out to compare the effectiveness of a single PHV on functioning with group-session intervention and a control group receiving typical care offered by the municipality revealed favourable effects on functioning in both intervention groups. In these two groups, at the one-year follow-up tiredness in carrying out daily activities was significantly diminished in comparison with that in the control group, but after the intervention ended the effect was diluted in the two-year follow-up and there was no significant difference between the groups (Behm et al. 2016). This result is consistent with that in other studies, indicating that long-lasting effects of interventions aimed at older people are only achieved through long-term support after the initial intervention (Stuck et al. 2002).

Effects on functioning

Of the 13 studies reporting favourable effects of PHVs on functioning (Table 5), seven reported positive effects on ADL (Behm et al. 2016, Bleijenberg et al. 2016, Gustafsson et al. 2012, Kono et al. 2012, 2016, Stuck et al. 1995, Stuck et al. 2000) and two on IADL (Fabacher et al. 1994, Stuck et al. 2000). Furthermore, one suggested effects on the prevalence of frailty (Fairhall et al. 2015), one on the number of falls and prevalence of falls with consequences (Imhof et al. 2012), and one on the prevalence of fatigue in performing daily tasks (Schraeder et al. 2001). One study showed effects on performing physical and social leisure activities (Granbom et al. 2017). In many studies reporting some favourable results on functioning, not all measured dimensions of functioning were affected (Behm et al. 2016, Fabacher et al. 1994, Granbom et al. 2017, Gustafsson et al. 2012,

Imhof et al. 2012, Stuck et al. 2000) or only a subgroup of participants benefitted from the intervention (Kono et al. 2012). Usually there were no differences between groups in IADL (Bleijenberg et al. 2016, Bleijenberg et al. 2017, Kono et al. 2012, Kono et al. 2016, Stuck et al. 1995), although a few studies suggest that the intervention group retained functioning in IADL significantly better than the control group (Fabacher et al. 1994, Stuck et al. 2000). Of the 24 studies exploring the effectiveness of PHVs on functioning, eleven did not show favourable effects (Bouman et al. 2008a, Brettschneider et al. 2015, McEvan et al. 1990, Hebert et al. 2001, Metzelthin et al. 2015, Pathy et al. 1992, Ploeg et al. 2010, Van Hout et al. 2010, Van Rossum et al. 1993, Vetter et al. 1984), and one study revealed favourable results on well-being without a decline in functioning (Melis et al. 2008).

Thus, the studies indicated some favourable findings on functioning, although the effects did not usually cover all measured dimensions of functioning and sometimes were relatively small. Comparison of studies and their results is challenging as a result of heterogeneity in interventions, in outcome measures used and in methods of reporting the outcomes. The effectiveness of PHVs on functioning, the target group that would benefit the most, and the characteristics of intervention most essential to enhance or maintain functioning remain unclear. These findings are similar to those in earlier reviews, where PHVs have been found to have a small effect on functioning, although specific aspects of target groups and interventions related to favourable effects have not been recognized (Beswick et al. 2008, Markle-Reid et al. 2006, Huss et al. 2008, Mayo-Wilson et al. 2014). However, it seems that extended follow-up and support to maintain the functioning of older participants is needed after intervention, since the effects of PHVs on functioning may quickly become diluted (Stuck et al. 2002, Schraeder et al. 2001, Behm et al. 2016).

Another challenge in supporting the functioning of older people by means of PHVs is finding the right target group for intervention. Well-functioning older people have benefitted more in some earlier studies than older people with limitations in functioning (Markle-Reid et al. 2006, Stuck et al. 1995, 2000, 2002). However, in this literature review there was no clear difference in functioning outcomes between studies that included older people with better functional status compared with those that included only those with functional limitations.

2.3.2 *Effectiveness of PHVs on older adults' HRQoL and well-being*

Self-rated health (SRH), well-being and HRQoL have been used in PHV studies to measure the effects that health-promotion interventions have on older people's QOL. In these studies, typically, well-being has been focused on positive aspects of life, e.g. morale and optimism (Vaarama 2009,

Van Rossum et al. 1993), whereas HRQoL has been focused on the effects on current health and functional status of an older person (Cummins 1997, McEvan et al. 1990). The effects of PHVs on well-being and HRQoL of older people have been studied less than their effects on functioning. However, this area of research has grown in more recent PHV studies. In this review the first health-promotion interventions aimed to maintain or improve well-being or HRQoL were performed in the 1990s (McEvan et al. 1990, Van Rossum et al. 1993).

Measures

Well-being and HRQoL have been assessed by means of a variety of measures in the PHV studies under review. The most commonly used measures in HRQoL have been EuroQol-5D (EQ-5D) (EuroQol Group 1990, Bleijenberg et al. 2016, Brettschneider et al. 2015, Fairhall et al. 2015, Metzelthin et al. 2015, Yamada et al. 2003), Short Form 36 (SF-36) and RAND-36 (Ware et al. 1992, Bleijenberg et al. 2016, Bouman et al. 2008a, Byles et al. 2004, van Hout et al. 2010). The Nottingham health profile (Hunt et al. 1986, McEvan et al. 1990), the McMaster Health Index (Chambers et al. 1982, McEvan et al. 1990), The Health Utilities Index Mark 3 (Furlong et al. 2001, Ploeg et al. 2010), and WHOQOL-Bref (Skevington et al. 2004, Imhof et al. 2012) were also used to measure HRQoL. The Philadelphia morale scale was used in one study to measure overall QOL (Lawton et al. 1975, McEvan et al. 1990). In some studies a separate numeric scale (e.g. rate your health between 0 [poor health] and 10 [excellent health]) (Van Rossum et al. 1993) or a visual analogue scale (VAS) (Sahlen et al. 2006) were used for measuring SRH. Well-being was measured in five studies, with different scales and measures (Bleijenberg et al. 2016, Crawford Shearer et al. 2010, Hebert et al. 2001, Sahlen et al. 2006, Van Rossum et al. 1993). Other items related to QOL measured in the PHV studies were depression or mental well-being (Bouman et al. 2008a, Brettschneider et al. 2015, Melis et al. 2008, Shapiro et al. 2002, Van Rossum et al. 1993), loneliness (Bouman et al. 2008a, Van Rossum et al. 1993), social relationships or social support (Bouman et al. 2008a, Hebert et al. 2001, Sahlen et al. 2006, Shapiro et al. 2002) and environmental mastery (Bouman et al. 2008a, Shapiro et al. 2002).

Characteristics of target groups and interventions

The mean age of the participants varied between 74 years and 85 years in the different studies. The participants were community-dwelling older people. In nine studies a decline in functioning was used as an inclusion criterion (Bleijenberg et al. 2016, Fairhall et al. 2015, Hebert et al. 2001, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Shapiro et al. 2002, van Hout et al. 2010, Yamada et al. 2003). Most of the studies exploring the effects of PHVs on well-being or HRQoL

did not have a large number of exclusion criteria. However, relatively commonly used exclusion criteria were terminal illness (Bleijenberg et al. 2016, Fairhall et al. 2015, Imhof et al. 2012, van Hout et al. 2010) and cognitive impairment (Brettschneider et al. 2015, Crawford Shearer et al. 2010, Fairhall et al. 2015, Imhof et al. 2012, van Hout et al. 2010).

Multiprofessional intervention was used in four studies (Byles et al. 2004, Brettschneider et al. 2015, Fairhall et al. 2015, Metzelthin et al. 2015) and a single professional (usually a nurse) delivered the intervention in thirteen of the studies (Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, Crawford Shearer et al. 2010, McEvan et al. 1990, Hebert et al. 2001, Imhof et al. 2012, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Sahlen et al. 2006, Shapiro et al. 2002, van Hout et al. 2010, Van Rossum et al. 1993, Yamada et al. 2003) exploring effects of PHVs on well-being and HRQoL. The intensities of the interventions varied, from one to two visits (Bleijenberg et al. 2016, Byles et al. 2004, McEvan et al. 1990) to at least ten visits (Fairhall et al. 2015). The duration of the intervention varied between three months (Crawford Shearer et al. 2010, Melis et al. 2008) and 36 months (Byles et al. 2004, Van Rossum et al. 1993).

Effects on well-being and HRQoL

Of the studies on the effects of PHVs, seven suggested favourable results on well-being or HRQoL (Byles et al. 2004, Crawford Shearer et al. 2010, McEvan et al. 1990, Melis et al. 2008, Pathy et al. 1992, Shapiro et al. 2002, Yamada et al. 2003), whereas twelve did not show positive effects on well-being or HRQoL (Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, Fairhall et al. 2015, Hebert et al. 2001, Imhof et al. 2012, Metzelthin et al. 2015, Ploeg et al. 2010, Sahlen et al. 2006, Sorensen et al.1988, van Hout et al. 2010, Van Rossum et al. 1993). Favourable effects were found on general health (Byles et al. 2004, Pathy et al. 1992, Yamada et al. 2003), well-being, morale, life satisfaction and emotional reactions (McEvan et al. 1990, Melis et al. 2008, Shapiro et al. 2002), social relationships and loneliness (Byles et al. 2004, McEvan et al. 1990), and mastery and purposeful participation in reaching personal goals (Crawford Shearer et al. 2010, Shapiro et al. 2002). One study revealed a favourable effect in a subgroup of participants who rated their own health as poor at baseline (Yamada et al. 2003).

2.3.3 *Effectiveness of PHVs on use and costs of healthcare services and their cost-effectiveness*

One of the main aims of PHV interventions has been economic: to reduce the use of demanding healthcare and social services, such as hospitalization and institutionalization (Elkan et al. 2001, Markle-Reid et al. 2006, Stuck et al. 2002, Tappenden et al. 2012). The hypothesis is that by supporting functioning and intervening in connection with disabilities and illnesses at an early

stage, PHV interventions may reduce costly specialist care and institutionalization (Elkan et al. 2001, Markle-Reid et al. 2006, Stuck et al. 2002). Earlier PHV studies were focused more on exploring the effects of PHV intervention on institutionalization (e.g. nursing home admissions) and primary-care use (Gunner-Svensson et al. 1984, Fabacher et al. 1994, Stuck et al. 1995, van Rossum et al. 1993, Vetter et al. 1984). Although most of these studies concerned some dimensions of services use or costs, only a few explored the cost-effectiveness of PHV intervention (Brettschneider et al. 2015, Fairhall et al. 2015, Melis et al. 2008, Metzelthin et al. 2015, Stuck et al. 1995, Tappenden et al. 2012).

Measures

Altogether, 27 studies reported outcomes concerning some variables related to healthcare and social services use or costs (Bleijenberg et al. 2016, Brettschneider et al. 2015, Byles et al. 2004, Dalby et al. 2000, McEvan et al. 1990, Fabacher et al. 1994, Fairhall et al. 2015, Frese et al. 2012, Gunner-Svensson et al. 1984, Hebert et al. 2001, Hendriksen et al. 1984, Imhof et al. 2012, Kono et al. 2013, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Pathy et al. 1992, Ploeg et al. 2010, Sahlen et al. 2006, 2008, Schraeder et al. 2001, Shapiro et al. 2002, Sorensen et al.1988, Stuck et al. 1995, Stuck et al. 2000, van Hout et al. 2010, van Rossum et al. 1993, Vetter et al. 1984). Institutionalization and hospitalization were the most reported outcomes, with institutionalization rates reported in 15 studies (Bleijenberg et al. 2016, Brettschneider et al. 2015, Byles et al. 2004, Dalby et al. 2000, Fabacher et al. 1994, Fairhall et al. 2015, Gunner-Svensson et al. 1984, Hebert et al. 2001, Melis et al. 2008, Metzelthin et al. 2015, Shapiro et al. 2002, Stuck et al. 1995, Stuck et al. 2000, van Hout et al. 2010, van Rossum et al. 1993) and rates of hospitalization reported in 14 (Bleijenberg et al. 2016, Byles et al. 2004, Fabacher et al. 1994, Fairhall et al. 2015, Imhof et al. 2012, Kono et al. 2013, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Schraeder et al. 2001, Stuck et al. 1995, Stuck et al. 2000, van Hout et al. 2010, van Rossum et al. 1993). Other reported variables related to health- and social-care use were primary-care use, general practitioner (GP) visits and/or consultations, emergency department visits, outpatient-clinic visits and community services use including, for example, meals-on-wheels, home nursing care and home help.

Total costs of healthcare and social services were reported in eleven studies (Brettschneider et al. 2015, Fairhall et al. 2015, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Sahlen et al. 2008, Schraeder et al. 2001, Stuck et al. 1995, Stuck et al. 2000, van Rossum et al. 1993) and total healthcare costs were reported in five studies (Kono et al. 2013, Melis et al.

2008, Metzelthin et al. 2015, Ploeg et al. 2010, van Rossum et al. 1993). A cost-effectiveness analysis was performed in five studies (Brettschneider et al. 2015, Fairhall et al. 2015, Melis et al. 2008, Metzelthin et al. 2015, Stuck et al. 1995).

Characteristics of target groups and interventions

The mean age of participants in the studies exploring services use and costs and cost-effectiveness varied from 72 years (Fabacher et al. 1994) to 85 years (Brettschneider et al. 2015, Imhof et al. 2012). In these trials the intensity of interventions varied from one visit (Bleijenberg et al. 2016, Byles et al. 2004, Dalby et al. 2000, Gunner-Svensson et al. 1984, Vetter et al. 1984) to over ten visits (Fairhall et al. 2015). The intervention was multiprofessional in four of the PHV studies exploring services use and costs (Brettschneider et al. 2015, Byles et al. 2004, Fairhall et al. 2015, Metzelthin et al. 2015). In the other studies, the intervention was delivered by a single professional, most often a nurse (Table 5).

The duration of intervention varied from three months (Brettschneider et al. 2015, Melis et al. 2008) to 36 months (Byles et al. 2004, Stuck et al. 1995, Stuck et al. 2000, van Rossum et al. 1993) in both the studies with favourable findings and those that did not detect favourable differences. However, in the studies with short intervention the follow-up period tended to be short. Thus, the stability of outcomes over time cannot be assessed in the studies with short interventions.

Effects on use and costs of services

In studies exploring the effects of PHVs on healthcare and social services use and costs, ten reported some favourable outcomes (Fairhall et al. 2015, Hendriksen et al. 1984, Imhof et al. 2012, Kono et al. 2013, Melis et al. 2008, Sahlen et al. 2008, Shapiro et al. 2002, Stuck et al. 1995, 2000, van Rossum et al. 1993). Only three studies showed the intervention group to be less likely to be institutionalized (Melis et al. 2008, Shapiro et al. 2002, Stuck et al. 1995), and one study suggested a higher risk of institutionalization in the intervention group (Byles et al. 2004). Four studies showed less hospitalization in the intervention group (Imhof et al. 2012, Melis et al. 2008, Kono et al. 2013, van Rossum et al. 1993), although one of these showed this favourable effect only in connection with costly hospitalizations (Kono et al. 2013).

The intervention group used more primary care or GP services in four studies (Bleijenberg et al. 2016, Metzelthin et al. 2015, Stuck et al. 1995, Stuck et al. 2000) and more community services in two studies (van Rossum et al. 1993, Vetter et al. 1984). These results were to be expected, as the professionals delivering the home visits often advised the participants to contact their GP, other

primary-care professional or community services if any risks were detected. In one study, increased use of GP services occurred in connection with a lower risk of institutionalization (Stuck et al. 1995). In another study, greater use of community services occurred in connection with lower use of specialist outpatient clinic services and less hospitalization in the intervention group (van Rossum et al. 1993).

None of the studies (n = 11) showed any statistically significant differences in total costs between intervention and control groups. Some variation in total costs between the groups was found, with three studies suggesting slightly lower total costs (Kono et al. 2016, Ploeg et al. 2012, Sahlen et al. 2008) and five studies suggesting slightly higher total costs (Brettschneider et al. 2015, Fairhall et al. 2015, Metzelthin et al. 2015, Schraeder et al. 2001, van Rossum et al. 1993) in the intervention group. However, these differences were not reported to be statistically significant. One study showed healthcare costs to be significantly higher in the intervention group, although there was no significant difference in total costs (Metzelthin et al. 2015). The participants in the intervention group in this study were more disabled and more frail at baseline, which might explain the difference detected in healthcare costs (Metzelthin et al. 2015).

Of the five studies exploring cost-effectiveness, three showed the intervention to be cost-effective (Fairhall et al. 2015, Melis et al. 2008, Stuck et al. 1995). The level of costs at which the intervention was evaluated to be cost-effective varied from $6,000 per gained disability-free year (Stuck et al. 1995) to willingness to pay 34,000€ to $50,000 per successfully treated participant (Fairhall et al. 2015, Melis et al. 2008). Two studies exploring cost-effectiveness showed the intervention not to be cost-effective (Brettschneider et al. 2015, Metzelthin et al. 2015).

The participants tended to be older in the studies which suggested favourable effects in services use and/or costs, with five studies having participants over 80 years old on average (Fairhall et al. 2015, Imhof et al. 2012, Melis et al. 2008, Stuck et al. 1995, Stuck et al. 2000) and only three studies with participants with a mean age of 80 years or younger (van Rossum et al. 1993, Sahlen et al. 2008, Shapiro et al. 2002). In the studies which did not show favourable effects in services use and/or costs, the mean age of the participants was over 80 years in only three studies (Brettschneider et al. 2015, Ploeg et al. 2010, van Hout et al. 2010), and 80 years or younger in nine studies (Bleijenberg et al. 2016, Dalby et al. 2000, Fabacher et al. 1994, Gunner-Svensson et al. 1984, Hebert et al. 2001, Kono et al. 2013, Kono et al. 2016, Metzelthin et al. 2015, Schraeder et al. 2001).

In the studies exploring the effects of PHVs on healthcare and social services use and costs, functional decline was used as an inclusion criterion in 12 (Bleijenberg et al. 2016, Dalby et al.

2000, Fairhall et al. 2015, Hebert et al. 2001, Kono et al. 2013, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Schraeder et al. 2001, Shapiro et al. 2002, van Hout et al. 2010). In those that suggested favourable effects on services use and costs only three of eight studies included functional decline as an inclusion criterion (Fairhall et al. 2015, Melis et al. 2008, Shapiro et al. 2002), whereas of the studies that did not detect differences in services use and costs in favour of the intervention nine of sixteen used functional decline as an inclusion criterion (Bleijenberg et al. 2016, Dalby et al. 2000, Hebert et al. 2001, Kono et al. 2013, Kono et al. 2016, Metzelthin et al. 2015, Ploeg et al. 2010, Schraeder et al. 2001, van Hout et al. 2010). However, in one study it was noted that the intervention was more likely to be cost-effective in the "very frail" subgroup than among those with better functional ability (Fairhall et al. 2015).

The interventions which produced some favourable results on use and costs of healthcare and social services tended to be more intensive. Most of the interventions producing some favourable results included four (Imhof et al. 2012, Shapiro et al. 2002, Stuck et al. 2000, Stuck et al. 1995, van Rossum et al. 1993) to at least ten (Fairhall et al. 2015) visits, with only one intervention with two home visits producing favourable results (Sahlen et al. 2008). In studies which did not reveal favourable effects on services use and costs, most interventions included only one (Bleijenberg et al. 2016, Byles et al. 2004, Dalby et al. 2000, Gunner-Svensson et al. 1984, Vetter et al. 1984) to four (Fabacher et al. 1994, Kono et al. 2016, Schraeder et al. 2001, van Hout et al. 2010) visits, with only one study with a maximum of 12 contacts (Hebert et al. 2001).

2.3.4 *Effectiveness of PHVs on mortality*

Of the RCTs, 21 explored the effects of intervention on mortality (Table 5). Most studies did not reveal significant differences in mortality between the intervention and control groups. However, in seven studies the risk of dying was significantly lower in the intervention group (Brettschneider et al. 2015, Hendriksen et al. 1984, Pathy et al. 1992, Sahlen et al. 2006, Schraeder et al. 2001, Shapiro et al. 2002, Vetter et al. 1984). One study showed a lower risk of dying or becoming institutionalized in the intervention group vs. the control group (Frese et al. 2012).

There were no clear common characteristics in these seven studies. The mean age of participants varied from 69 years (Pathy et al. 1992) to 85 years old (Brettschneider et al. 2015) and decline in functioning was used as an inclusion criteria in two of these studies (Schraeder et al. 2001, Shapiro et al. 2002). In one study with favourable findings in mortality the intervention was multiprofessional (Brettschneider et al. 2015).

2.4 Summary of the literature review

Preventive home visits have been used for decades to support home-dwelling older people's functioning and to prevent admission to institutional care. Nurses have most commonly been the professionals implementing the intervention. However, multi- or interprofessional teams have been increasingly used in these interventions.

Comprehensive geriatric assessment has shown effectiveness as regards older people's functioning in a high number of trials. It has also been implemented as part of a multidimensional approach in PHVs. Since the 1990s HRQoL and well-being have been used as outcome measures in some PHV trials, most of these studies having been performed during the past 15 years. HRQoL is considered to be a patient-centred outcome. However, only five studies have explored the effects of PHVs on QALYs.

Of the 33 studies, 25 showed favourable effects of PHVs on some of the outcomes explored. Most of these studies did not show favourable effects in all the dimensions explored. Of the studies, eight did not show any favourable effects of PHV interventions on older people (Bouman et al. 2008a, Dalby et al. 2000, Gunner-Svensson et al. 1984, Hebert et al. 2001, Metzelthin et al. 2015, Ploeg et al. 2010, Sorensen et al.1988, van Hout et al. 2010). Although in many studies the findings were modest, this would suggest that PHVs have the potential to produce some favourable effects on functioning, well-being and HRQoL, mortality, and healthcare and social services use and costs.

The participants, interventions, durations of interventions and follow-ups, and outcomes used in the PHV studies were varied. Furthermore, these PHV studies were performed over a long time period, some even decades apart from each other. During time periods of this length, healthcare systems have changed considerably, which in turn changes the settings in which these studies were performed. These features create a challenge in comparing the studies, their results and what items might have been important in producing favourable results.

Although many of the studies have explored some effects of PHVs on the costs to healthcare and social services, there are only a few studies on the cost-effectiveness of these interventions. The number of older people is growing fast. Cost-effective preventive interventions and support in connection with multimorbid older people's QOL are needed. PHV interventions suggest some favourable effects on older people's functioning and well-being, but more research into their effectiveness on QOL and cost-effectiveness is needed.

3 Aims of the study

The aim of this study was to examine the effects of preventive home visits to older people on their health-related quality of life (HRQoL) and the use and costs of healthcare and social services.

Research questions in the individual studies were as follows:

1. What is the evidence from earlier randomized controlled studies on the effects of PHVs on functioning, HRQoL, mortality and use and/or costs of healthcare and social services and cost-effectiveness of the effects of PHVs when reviewed systematically? (Study I and the update to the literature review).
2. What are the baseline findings and practicability of the PHV study on independent home-dwelling older adults (≥ 75 years of age)? (Study II).
3. What are the effects of a multiprofessional three-visit home-visit intervention programme on independent home-dwelling older adults (75+ years old) as regards their HRQoL and mortality in a two-year follow-up study? (Study III).
4. What are the effects of a multiprofessional three-visit home-visit intervention programme on independent home-dwelling older adults (75+ years old) as regards the use and costs of healthcare and social services in a two-year follow-up study? (Study IV).

4 Methods

4.1 Systematic literature review (I)

Study I is a systematic review of randomized controlled trials (RCTs) examining the effectiveness of preventive home visits on older people's use of health and social services, the costs involved and the effects achieved with intervention on older people's functioning, quality-of-life (QOL) and mortality. Furthermore, in the literature review of this dissertation RCTs exploring the effectiveness of PHVs on independent home-dwelling older people were included. This review updates the Article I review and expands its focus beyond use and costs of services. For the review, PHVs were defined as visits to community-dwelling older people, concerning multidimensional medical, functional, psychosocial, and/or environmental evaluation of their problems and resources.

Relevant RCTs were systematically sought in electronic databases (PubMed, Ovid Medline, Cochrane Database, DARE, and Cinahl) using keywords related to home visits for older people and economic analysis. The following terms were used: ((preventive OR prevention) AND (home care OR home nursing OR house calls OR home visit)) AND aged [MeSH Terms] AND (cost-effectiveness OR economic OR cost-benefit analysis OR costs and cost analysis OR health care costs OR hospital admissions OR nursing home admissions) in all fields. Search terms (aged OR elderly OR older people OR old) were used in databases where "aged" [MeSH Term] search was not possible. The original search was performed in May 2015, and it was repeated in February 2016 and August 2018. The earlier reviews and reference lists from earlier papers were hand-searched for additional studies. The original search revealed 19 RCTs. The search in August 2018 was performed using the same search method as in 2015 and 2016, without the search terms and inclusion criteria concerning use and costs of healthcare and social services. This supplementary search revealed an additional 14 RCTs (see flowchart, Figure 1).

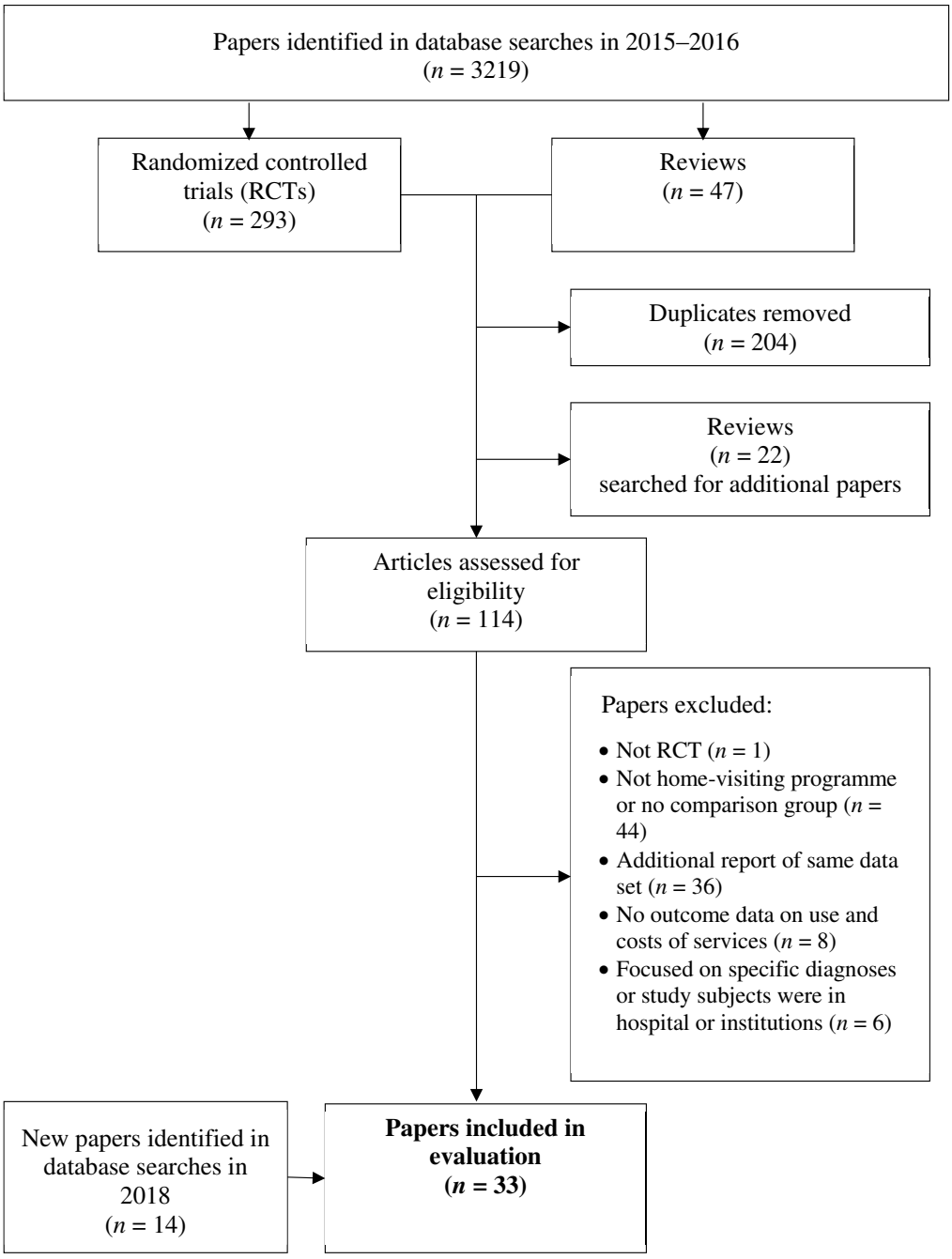

Figure 1. Flowchart of the systematic review.

The methodological quality of the included studies was evaluated by two independent researchers according to a ten-criteria rating system. If differences of opinion emerged, they were taken to a third researcher and discussed between the reviewers until a consensus was reached. The rating system applied the criteria for randomized intervention trials used by Cochrane and collaborators (The Cochrane Collaboration 2011), the Evidence-Based Medicine Working Group (Guyatt et al. 1993, 1994) and the Joanna Briggs Institute MAStARI critical appraisal tool (The Joanna Briggs Institute 2011).

The 10 criteria are described in detail below:

(1) Inclusion and exclusion criteria are satisfactorily described.
(2) Groups are comparable at baseline.
(3) The study has sufficient statistical power to detect an effect and there was a strength calculation.
(4) The randomization method is adequately described and the assignment to treatment groups was truly random.
(5) The measurements and outcome measures are valid and well defined.
(6) The intervention is adequately described.
(7) The dropouts are described and the analyses take them into account.
(8) Intention-to-treat analysis is applied.
(9) A comparison is made in relation to outcome variables between the groups.
(10) The group assignment is blinded when assessing the outcomes.

Each criterion was considered to be worth 1 point. Each item was scored '+' if the criterion was fulfilled, '-' if the criterion was not fulfilled, '+/-' if the criterion was partly fulfilled, and '?' if no information was provided or information was unclear. Trials scoring 8–10 points were considered to be of high quality, whereas scores of 5–7 indicated moderate quality and < 5 indicated poor quality.

4.2 Study design and recruitment (II–IV)

In Studies II–IV we report the results and practicability of a randomized controlled trial exploring the effects of multiprofessional preventive home-visit intervention on independent home-dwelling older adults in the Hyvinkää area.

Older adults (≥ 75 years of age) living at home in Hyvinkää municipality (n = 2,692) were contacted by a post in May 2013. The sample was obtained from the population registry office. The information letter sent explained the trial and invited these older adults to participate in it. Of these, 1,143 returned the letter and showed interest in the study. A postal survey was sent to them and a

study nurse contacted them. The inclusion criteria for the study were: 75 years old or more, independently home-dwelling without home help/nursing services, Finnish-speaking, able to provide informed concent, and living permanently in Hyvinkää. Based on the survey, 968 of those who returned the letter fulfilled the inclusion criteria. Of these, the first consecutive 422 persons giving their informed consent were recruited to the study.

The follow-up time for the study was two years, and the same study letter was sent to participants at baseline and at one- and two-year time-points.

The flow of participants and attrition rates are shown in Figure 2. The 15D data was missing for three participants in the intervention group and five participants in the control group only on one-year timepoint, and for 24 participants in the intervention group and 33 in the control group only on two-years timepoint. All participants with at least one data point on 15D on follow-up were included in the analyses, therefore 89% (n = 189) of the intervention group and 87% (n = 185) of the control group were included in analyses. The use and costs of services data were collected for all participants until death or two-years time point.

4.3 Ethical considerations (II–IV)

The study protocol for the RCT was approved by the Ethics Committee of Helsinki University Hospital (no. 215/13/03/00/12, year 2012). All participants provided written, informed consent before participation, after receiving oral and written information on the study protocol. Those participating in the study were able to provide informed concent and had no severe cognitive impairment which would have prevented this.

4.4 Outcome measures (II–IV)

For the primary outcome measure we used the 15-dimensional instrument (15D) to assess HRQoL (Sintonen 2001). The 15D is a comprehensive, generic, 15-dimensional assessment scale. It can be used both as a profile measure and as a single index score. The single index score on a scale from 0 (poorest HRQoL) to 1 (excellent HRQoL) is calculated from the descriptive system of health state. The dimensions of the 15D questionnaire are mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity (Sintonen 2001).

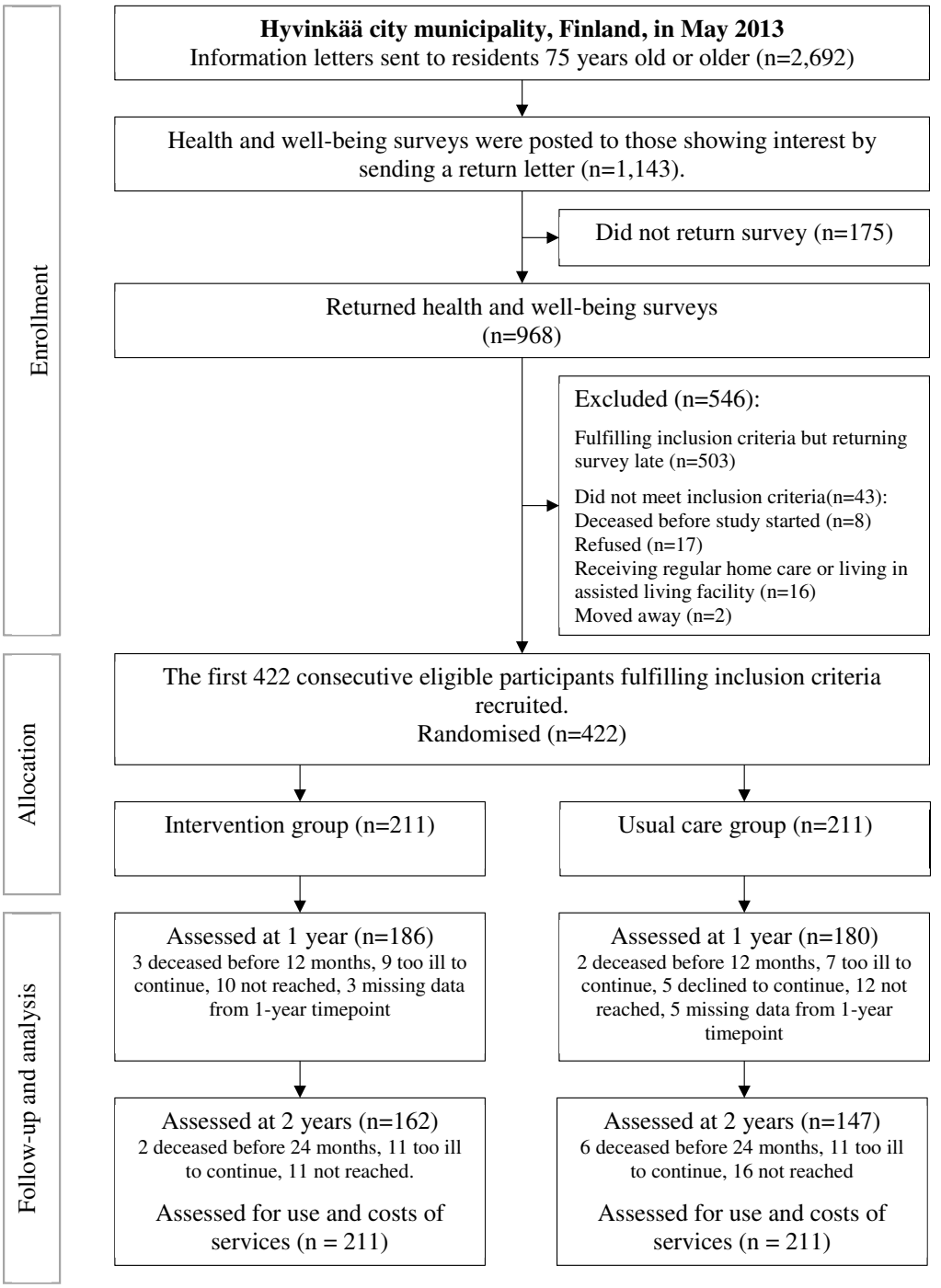

Figure 2. Flow chart of study participant selection, randomization, drop-outs and analyses.

The 15D is a brief questionnaire which is designed to be self-administered (Sintonen 2001). It correlates well with other HRQoL measures and has good discriminative validity and prognostic validity in aged populations (Strandberg et al. 2006). It has shown better discriminatory power than the Nottingham Health Profile (Sintonen 2001, Hunt et al. 1986), and it is sensitive to changes after healthcare intervention (Kattainen et al. 2005). The minimum important change in HRQoL measured by the 15D instrument is 0.015 for improvement and -0.015 for deterioration (Alanne et al. 2015).

Secondary outcome measures included use and costs of healthcare and social services, and mortality, which were retrieved from medical records and central registers up to two years after the first home visit.

A feedback survey was performed in the intervention group after the home visits to assess the practicability of the intervention. The items in the survey were designed to explore the satisfaction of participants and to be consistent with the general aims of the intervention. The questions were: (1) Did you find the home visits beneficial? (2) Did you get new information about available services? (3) Did you receive new information on supporting or improving your health? (4) Has your health or functioning improved due to the home visits? (5) Has your well-being increased? (6) Do you wish to receive similar home visits in the future if there is an opportunity? The options for answering were “yes”, “no” and “cannot say”. The questionnaire was sent together with the one-year follow-up survey and answered anonymously.

4.5 Data collection (II–IV)

At baseline we collected demographic data (age, gender, education, marital status), current height and weight, current medications, use of assistive devices, risk factors (smoking, use of alcohol, falls during the past six months), exercise habits, medical history and diagnoses (list of diseases with yes/no options) and HRQoL via the 15D measure. The data was collected by way of similar postal surveys at baseline and at follow-up at one-year and two-year time points. The use of prescription drugs was confirmed from medical records. We calculated the Charlson comorbidity index score (Charlson et al. 1987) based on diagnoses to evaluate the overall disease burden.

Data on the use and costs of healthcare and social services were collected in detail for one year before the study and then for two years. All visits to primary-care physicians and nurses and other healthcare specialists (such as physiotherapists, occupational therapists, nutritionists and foot therapists), specialist doctor’s ambulatory visits, home-care visits, day-centre days and days spent in

institutions (various hospitals, nursing homes or long-term care hospitals) were retrieved from registers, patients' medical records in their primary-care facilities and all their area hospitals, and from social care registers.

Costs of services were retrieved from the 2011 report by the Finnish National Institute for Health and Welfare as mean unit costs for Finland (Kapiainen et al. 2011) and correction was made for the inflation rate based on the official cost-of-living index. The number of health and social-care services utilization units were multiplied by the cost prices for each unit to calculate the total costs. The intervention costs were calculated according to the mean unit costs for the three home visits performed. Costs are presented in euros (€).

Mortality dates were retrieved from central registers at the end of the study.

4.6 Randomization (II–IV)

The first 422 consecutive persons who fulfilled the inclusion criteria and gave their informed consent were randomized into intervention (n = 211) and control (n=211) groups. Randomization was performed using computer-generated random numbers from Research Randomizer (Urbaniak et al. 2013), seeded by the computer's clock. Two randomizations were performed as spouses (n = 128) were randomized together to avoid dilution of the intervention effect. The control group received their typical care including the normal health and social care offered by the municipality, and the intervention group received the preventive home visits in addition to their typical care.

4.7 Intervention (II–IV)

The intervention consisted of multiprofessional home visits that utilized CGA. Professionals specially trained for the task delivered the three home visits. They also received written and oral instructions on performing the home visits. The professionals could consult and hold meetings with a physician of a geriatric ward, and with each other. The first home visit was delivered by a nurse, the second by a physiotherapist and the third by a social worker over a six- to nine-month period from the start of the intervention. The duration of the visits varied from half an hour to one and a half hours per visit (Table 7).

The professionals used validated, structured tests for assessment at the home visits. They had unified instructions on the actions to be taken and recommendations to be given, based on the assessment results. In addition, the professionals gave individualized guidance and made individualized recommendations and referrals to other professionals and service providers according to the needs and wishes of the participant. The assessments used, guidance given, recommendations, and actions taken are described in Tables 6 and 7.

Table 6. Instruments used in assessment.

Instrument used in CGA during the PHV	**Domain assessed**	**Cut-off point for intervention**
MMSE (Folstein et al. 2975)	Cognition	≤ 24 points / 30
GDS-15 (de Craen et al. 2003)	Depression	> 6 points / 15
MNA screening (Guigoz et al. 2002)	Nutrition	< 12 points / 14
Barthel scale (Mahoney et al. 1965)	Functioning: Activities of daily living	Tailored / max 100 points
Lawton IADL scale (Lawton et al. 1969)	Functioning: Instrumental activities of daily living	Tailored to needs and wishes of participant / max 8 points
RAI-HC (Hirdes et al. 2008, Morris et al. 1999)	Comprehensive assessment in a variety of domains	As RAI Clinical Assessment Protocols suggest
FROP-Com screen (Russell et al. 2008)	Risk of falls Balance	> 3 points / 9
Jamar (Abizanda et al. 2012)	Muscle strength by hand-grip strength	< 32 kg for males and < 15 kg for females
5 repetition chair-stand test (Guralnik et al. 1994)	Physical functioning Risk of disability	< 13.5 s

Abbreviations: CGA = comprehensive geriatric assessment; PHV = preventive home visit; MMSE = Mini-Mental State Examination (Folstein et al. 1975); MNA = Mini Nutritional Assessment (Guigoz et al. 2002); RAI-HC = interRAI Home Care Assessment System (Hirdes et al. 2008, Morris et al. 1999); GDS-15 = Geriatric Depression Scale (de Craen et al. 2003); IADL = Instrumental Activities of Daily Living (Lawton et al. 1969); FROP-Com = Falls Risk for Older People – Community setting screen (Russell et al. 2008)

Table 7. Components of preventive home visit (PHV) intervention as categorized by Fagerström et al. 2009.

Categories	1st visit, Nurse	2nd visit, Physiotherapist	3rd visit, Social worker
Screening, observation and evaluation	RAI-HC (Hirdes et al. 2008, Morris et al. 1999), MMSE (Folstein et al. 1975), MNA screen (Guigoz et al. 2002), ADL on Barthel scale (Mahoney et al. 1965), GDS-15 (de Craen et al. 2003), IADL (Lawton et al. 1969) Physiological measurements: blood pressure, blood glucose	FROP-Com screen (Russell et al. 2008), hand-grip strength, Jamar (Abizanda et al. 2012), chair-stand test (Guralnik et al. 1994) Assessed the need for aids	RAI-HC (Hirdes et al. 2008, Morris et al. 1999) Activities of Daily Living (ADL and IADL) (Mahoney et al. 1965, Lawton et al. 1969) Assessed social functioning and service needs
Guidance and information	Health and social services offered by the municipality; Local volunteer and third-party organizations	Physical activity recommendations; Physiotherapy services of the municipality for individuals and groups; Services offered by local volunteer and third-party organizations	Financial and other benefits for older people; Social services provided by the municipality; Services and benefits from the Finnish Social Insurance Institution; Local volunteer and third-party organizations
Recommendations and support	Referral to GP or community nurse if: Blood pressure ≥ 140/85 (under 80 years old) or ≥ 150/85 (80 years or over), blood glucose fasting > 6.1 or 2 hours after eating > 7.8, GDS-15 score ≥ 6 BMI > 35 or MNA screening < 12, as RAI Clinical Assessment Protocols suggest, other concerns of acute or chronic conditions Referred to memory clinic if MMSE ≤ 24 Recommendations: service needs assessment, physiotherapy, exercise group, or third-party service provider according to individual needs	Personalised instructions and guidance in physical training Referred to GP or community nurse if concerns of acute or chronic condition arise Referred to group training or physiotherapist appointment arranged according to individual needs	If RAI Clinical Assessment Protocols highlight, or deficits of functioning not addressed earlier were detected, referred to GP, community nurse or service needs assessment. Need for services or financial benefits: helped the participant to fill in necessary forms, contact the service provider in question, or arranged an appointment According to individual needs, recommendations for: emergency phone, friend service, day care, cleaning service or other third-party service provider
Individualised recommendations	Received individualised instructions for further actions and/or were referred to GP or other service (n = 104)	Personalised guidance for physical training for all (n = 211); Instructions to register for group training (n = 3); Instructions to book a personal physiotherapist appointment (n = 2)	Individualised instructions/help to contact a service provider, apply for financial benefits, or arrange an appointment (n = 76)
Duration of visit	1.0–1.5 hours	1.0–1.5 hours	0.5–1.5 hours

Abbreviations: RAI-HC = interRAI Home Care Assessment System (Hirdes et al. 2008, Morris et al. 1999); MMSE = Mini-Mental State Examination (Folstein et al. 1975); MNA = Mini Nutritional Assessment (Guigoz et al. 2002); ADL = Activities of Daily Living (Mahoney et al. 1965); GDS-15 = Geriatric Depression Scale (de Craen et al. 2003); IADL = Instrumental Activities of Daily Living (Lawton et al. 1969); FROP-Com = Falls Risk for Older People – Community setting screen (Russell et al. 2008); GP = general practitioner; BMI = Body Mass Index

4.8 Statistical analyses

4.8.1 *Systematic review (I)*

In the systematic review (Study I) the RCTs were evaluated for their quality, outcomes and treatment effects. From each study the following data were extracted: location of the study setting, sample size, age of participants, gender distribution (if mentioned), inclusion and exclusion criteria, description of the intervention, duration and intensity of the intervention, deliverer of the home visits, outcome measures, and intervention effects.

4.8.2 *Intervention study (II–IV)*

In the intervention study (Studies II–IV) a power calculation was performed to estimate the sample size based on 15D measures. The calculation was based on a change of 0.03 points in the 15D score (Sintonen 2001). The standard deviation (SD) of 15D was 0.15 in prior studies (Pitkala et al. 2008). For a type 1 error of 5% and a power of 80% a minimum sample size of 196 study participants was needed per study arm, based on the calculation.

The primary outcome (15D) was analysed according to a modified intention-to-treat principle. Participants who had a baseline assessment and at least one follow-up assessment were included in the analysis. In all analyses the level of statistical significance was 5% ($p < 0.05$).

Regarding the baseline findings (Studies II–IV), the groups are described in terms of proportions for categorial variables and means with standard deviations for continuous variables. For categorial variables, the χ^2 test and Fisher's exact test were used to test differences between the intervention and control groups. Student's *t*-test and the Mann–Whitney *U*-test were used for continuous variables, as appropriate. Multiple imputations were performed for some missing 15D items, using the method of chained equations and five sets of imputations, as implemented in the Stata ice add-on.

Mean changes in the 15D score over time (Studies III–IV) were assessed using the mixed-model repeated measures method with treatment, visit, and treatment–visit interaction as fixed effects. The model included age, sex, and the baseline score as covariates in Study III. We used Cox proportional hazards regression for the estimation of age, gender, and Charlson comorbidity index adjusted hazard ratios (mortality as outcome variable). In Study IV, the model included the baseline score as a covariate. Differences in the mean change in the 15D score between the intervention and control groups are described, with 95% confidence intervals (CIs).

In Study IV, Student's *t*-test, the bootstrap-type *t*-test, or the chi-square test were used to make statistical comparisons between the groups, as appropriate. Generalized linear models with a log-link function and a Gaussian distribution were used to model means ratios (with 95% CIs) for costs. Bias-corrected bootstrapping (10,000 replications) was used to obtain the CIs for the means because of the skewed distribution of the use and costs of healthcare and social services. The bootstrap type t-test and generalized nonparametric Hodges-Lehmann median differences were used for comparisons between the groups for costs. In the analysis of use and costs of healthcare and social services all randomized participants were included (intention-to-treat) (Study IV).

In Study IV, outcomes for the cost-utility analysis are expressed in terms of generic quality-adjusted life-years (QALYs), measured using HRQoL (15D instrument). The cost-utility analysis was performed in relation to QALY derived from the area under the curve calculation for the 15D score from baseline to last follow-up. For the 15D and QALY analysis all participants who completed the baseline assessment and at least one follow-up assessment were included. To avoid bias from missing data an imputation of missing follow-up observations of 15D (IG n = 22, CG n = 26) was created for analysing QALY using multiple imputation by chained equations (Royston 2004). All analysis variables were included in the imputation model. Multiple data sets (n=10) were generated to account for the uncertainty in imputed data.

In Study IV, the incremental cost-effectiveness ratio (ICER) was evaluated as the ratio of the mean difference in cost to the mean difference in effect. To manage the uncertainty around point-estimates of ICERs a bootstrap resampling with several (5000) datasets was created by resampling from the original data. Bootstrapped ICERs are presented on an incremental cost-effectiveness plane, where the vertical axis represents the difference in costs and the horizontal axis represents the difference in effectiveness in QALYs. On the vertical axis, costs increase upwards ("north") and decrease downwards ("south") and on the horizontal axis the effectiveness increases to the right ("east") and decreases to the left ("west"). Thus, the "north-east" quadrant represents the possibility of treatment costing more and being less effective than regular care, whereas the "south-west" quadrant represents the possibility of treatment being less costly and more effective. The number of estimates falling within each quadrant is denoted in percentages. These results of ICER bootstrap iterations plotted on the cost-effectiveness plane reflect the variability within the original study sample. Statistical analyses were performed using Stata statistical software version 15.0 (StataCorp, College Station, Texas, USA).

5 Results

5.1 Systematic review of the effects of PHVs (I)

The systematic search conducted in 2015 and in 2016 yielded 3219 articles, of which 293 were RCTs. Reviews were searched for additional papers. Duplicate articles and studies not relevant on the basis of the abstract were removed, leaving 114 articles (Figure 1).

These articles were examined in detail and 95 did not meet the inclusion criteria. Study protocols, studies that were not RCTs or did not have a comparison group, were not conducted on older people (aged 65+ years), did not include home visits, did not report outcome data on hospitalization, institutionalization or use or costs of healthcare and social services were excluded. Based on the definition of preventive home visits, studies that evaluated follow-up home visits directly related to recent hospital discharge, as well as studies in which the intervention was exclusively targeted to fall-prevention or cognitive function, were excluded. No language restrictions were imposed. We found 16 studies directly in the database searches, and three additional articles were found from earlier systematic reviews. The results of this initial search and evaluation of the 19 included trials are reported in Study I. Based on a supplementary systematic search conducted in August 2018, 14 studies were added to the review. The supplementary search was not restricted to PHV studies with reports on use and costs of services.

5.1.1 *Methodological quality of the trials*

A modified rating system was used to assess the methodological quality of the 33 RCTs examining the effects of PHV interventions targeted to older people (Table 8). Of the trials, 19 were considered as being of high methodological quality, with scores of eight to ten out of ten (Behm et al. 2016, Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, Byles et al. 2004, Crawford Shearer et al. 2010, Fairhall et al. 2015, Granbom et al. 2017, Gustafsson et al. 2012, Imhof et al. 2012, Kono et al. 2012, 2013, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Stuck et al. 1995, van Hout et al. 2010, van Rossum et al. 1993, Yamada et al. 2003) and 10 trials were considered as being of moderate methodological quality with scores of five to seven out of ten (Dalby et al. 2000, McEvan et al. 1990, Fabacher et al. 1994, Gunner-Svensson et al. 1984, Hebert et al. 2001, Sahlen et al. 2006, 2008, Schraeder et al. 2001, Shapiro et al. 2002, Stuck et al. 2000, Vetter et al. 1984).

Table 8. Evaluation of quality criteria fulfilment in randomized controlled trials (RCTs) examining the effects of preventive home visits targeted to home-dwelling older people.

Study	1)	2)	3)	4)	5)	6)	7)	8)	9)	10)	Total
Behm et al. 2016	+	+	+	+	+	+	+	+	+	?	9
Bleijenberg et al. 2016	+	+	+/-	+	+	+	+	+	+	?	8
Bouman et al. 2008a	+	+	+	+	+	+	+	+	+	?	9
Brettschneider et al. 2015	+	+	+	+	+	+	+/-	-	+	+	8
Byles et al. 2004	+	+	+	+	+	+	+	+	+	+	10
Crawford Shearer et al. 2010	+	+	+	+	+	+	+	+	+	+	10
Dalby et al. 2000	+	+	-	+	+	+/-	+/-	+/-	+	+/-	5
McEvan et al. 1990	+/-	+	+	-	+	+	+	+	+	-	7
Fabacher et al. 1994	+	+/-	?	+	+	+	-	?	+	?	5
Fairhall et al. 2015	+	+	+	+	+	+	+	+	+	+	10
Frese et al. 2012	+	+/-	+	?	+	+	-	-	+/-	?	4
Granbom et al. 2017	+	+	+	+	+	+	+	+	+	?	9
Gunner-Svensson et al. 1984	+/-	?	+/-	+/-	+	+	+	+	+	?	5
Gustafsson et al. 2012	+	+	+	+	+	+	+	+	+	?	9
Hebert et al. 2001	+/-	+	+	+/-	+	+	-	+	+	+	7
Hendriksen et al. 1984	+/-	+	+	-	+	+/-	+/-	?	+	?	4
Imhof et al. 2012	+	+	+/-	+	+	+	+	+	+	?	8
Kono et al. 2012, 2013	+	+	+	+	+	+	+	+	+	+	10
Kono et al. 2016	+	+	+	+	+	+	+/-	+	+	?	8
Melis et al. 2008	+	+	-	+	+	+	+	+	+	+	9
Metzelthin et al. 2015	+	+/-	+	+	+	+	-	+	+	+	8
Pathy et al. 1992	-	+	+/-	-	+	+/-	-	+	+	?	4
Ploeg et al. 2010	+	+	+	+	+	+	+/-	+/-	+	+	8
Sahlen et al. 2006, 2008	+	+/-	+/-	+/-	+	+	+	+	+	?	6
Schraeder et al. 2001	+	-	+	-	+	+	-	+	+	+	7
Shapiro et al. 2002	+	+	-	-	+	+	+	+	+	-	7
Sorensen et al. 1988	+/-	?	?	+/-	+/-	+	+	-	+/-	?	2
Stuck et al. 1995	+	+	+	+	+	+	+	+	+	?	9
Stuck et al. 2000	+	+	+	-	+/-	+	+	+	+	?	7
van Hout et al. 2010	+	+	+	+	+	+	+	+	+	?	9
van Rossum et al. 1993	+	+	+	+	+	+	+	+	+	+ /-	9
Vetter et al. 1984	+	+	+	-	+	+	+/-	-	+	-	6
Yamada et al. 2003	+	+	+	+	+	+	+	+	+	?	9

1) Inclusion and exclusion criteria are satisfactorily described. 2) Groups were comparable at baseline. 3) The study has sufficient statistical power to detect an effect or there was a proper power calculation. 4) The randomization method is adequately described and assignment to treatment groups was truly random. 5) The measurements and outcome measures are valid and well defined. 6) The intervention is adequately described. 7) The dropouts are described and the analyses take them into account. 8) Intention-to-treat analysis is applied. 9) A comparison is made in relation to outcome variables between the groups. 10) Group assignment is blinded when assessing the outcomes.
+ = criterion fulfilled (1 point); - = criterion not fulfilled; +/- = criterion partly fulfilled; ? = unclear;
High quality = 8–10, moderate quality = 5–7, poor quality = < 5 points

Only four of the studies were considered to be of poor methodological quality, with a score of four or less out of ten (Frese et al. 2012, Hendriksen et al. 1984, Pathy et al. 1992, Sorensen et al.1988). Methodological problems most often recorded were lack of information on blinding the group assignment when assessing the outcomes, poorly described randomization methods, inadequate description of the trial drop-outs and lack of power calculation, or low statistical power.

5.1.2 *Characteristics of the trials*

The trials included in the literature review were performed in Europe (n = 20) (Behm et al. 2016, Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, McEvan et al. 1990, Frese et al. 2012, Granbom et al. 2017, Gunner-Svensson et al. 1984, Gustafsson et al. 2012, Hendriksen et al. 1984, Imhof et al. 2012, Melis et al. 2008, Metzelthin et al. 2015, Pathy et al. 1992, Sahlen et al. 2006, Sorensen et al.1988, Stuck et al. 2000, Van Hout et al. 2010, Van Rossum et al. 1993, Vetter et al. 1984), the U.S.A. (n = 5) (Crawford Shearer et al. 2010, Fabacher et al. 1994, Schraeder et al. 2001, Shapiro et al. 2002, Stuck et al.1995,), Japan (n = 3) (Kono et al. 2012, Kono et al. 2016, Yamada et al. 2003), Canada (n = 3) (Dalby et al.2000, Hebert et al. 2001, Ploeg et al. 2010,) and Australia (n = 2) (Byles et al. 2004, Fairhall et al. 2015,). The included studies covered a total of 24,362 participants (range 59 to 4128).

All of the studies were performed on independent home-dwelling older people (inclusion criteria for studies included in the literature review). Of the studies, 14 were performed on frail subjects, individuals with a decline in functioning or people at risk of functional decline (Bleijenberg et al. 2016, Dalby et al.2000, Fairhall et al. 2015, Granbom et al. 2017, Gunner-Svensson et al. 1984, Hebert et al. 2001, Kono et al. 2012, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Schraeder et al. 2001, Shapiro et al. 2002, Van Hout et al. 2010, Yamada et al. 2003). Most of the studies had been performed on subjects aged 70 years or more (Bouman et al. 2008a, Byles et al. 2004, Dalby et al.2000, Fabacher et al. 1994, Fairhall et al. 2015, Frese et al. 2012, Gunner-Svensson et al. 1984, Melis et al. 2008, Metzelthin et al. 2015, Vetter et al. 1984, Yamada et al. 2003) or 75 years or more (McEvan et al. 1990, Hebert et al. 2001, Hendriksen et al. 1984, Ploeg et al. 2010, Sahlen et al. 2006, 2008, Shapiro et al. 2002, Sorensen et al.1988, Stuck et al.1995, Stuck et al. 2000, Van Hout et al. 2010, Van Rossum et al. 1993). Seven studies were focused on younger subjects (60+ or 65+) (Bleijenberg et al. 2016, Crawford Shearer et al. 2010, Granbom et al. 2017, Kono et al. 2012, Kono et al. 2016, Pathy et al. 1992, Schraeder et al. 2001) and four on the oldest olds (80+) (Behm et al. 2016, Brettschneider et al. 2015, Gustafsson et al.

2012, Imhof et al. 2012). The mean age of the participants in the studies varied between 72 to 86 years. Most of the trials included more female participants than males.

In most of the studies, the control and intervention groups were balanced at baseline. Differences between intervention and control groups at baseline were reported in five studies (Fabacher et al. 1994, Frese et al. 2012, Metzelthin et al. 2015, Sahlen et al. 2006, Schraeder et al. 2001). Of the included studies, two failed to report any baseline data on the participants (Gunner-Svensson et al. 1984, Sorensen et al.1988) and five failed to report any baseline data on the functioning or health status of the participants (Crawford Shearer et al. 2010, Granbom et al. 2017, Hendriksen et al. 1984, Pathy et al. 1992, Sahlen et al. 2006). Well-being or QOL of the participants at baseline were reported in 13 studies (Bleijenberg et al. 2016, Brettschneider et al. 2015, McEvan et al. 1990, Fairhall et al. 2015, Hebert et al. 2001, Imhof et al. 2012, Kono et al. 2012, Melis et al. 2008, Ploeg et al. 2010, Schraeder et al. 2001, Shapiro et al. 2002, van Hout et al. 2010, Yamada et al. 2003), and eight of the studies reported some baseline information on the cognitive status of the participants (McEvan et al. 1990, Fairhall et al. 2015, Imhof et al. 2012, Melis et al. 2008, Ploeg et al. 2010, Schraeder et al. 2001, Stuck et al. 2000, van Hout et al. 2010). Some information on the use and/or costs of healthcare and social services were reported at baseline in 12 studies (Bouman et al. 2008a, Brettschneider et al. 2015, Dalby et al. 2000, McEvan et al. 1990, Imhof et al. 2012, Metzelthin et al. 2015, Schraeder et al. 2001, Stuck et al. 1995, Stuck et al. 2000, van Hout et al. 2010, van Rossum et al. 1993, Yamada et al. 2003).

All of the studies included in the literature review reported the profession of the deliverer(s) of the intervention. Both multiprofessional PHV interventions (Behm et al. 2016, Brettschneider et al. 2015, Byles et al. 2004, Fairhall et al. 2015, Gustafsson et al. 2012, Metzelthin et al. 2015, Sorensen et al. 1988) and PHV interventions delivered by a single professional were explored in these studies. In two studies the intervention was delivered by a team of two professionals (Shapiro et al. 2002, Sorensen et al. 1988), three studies reported a multiprofessional team delivering the intervention (Behm et al. 2016, Brettschneider et al. 2015, Fairhall et al. 2015) and three studies reported a multiprofessional support team and meetings for the single professionals delivering the intervention (Byles et al. 2004, Gustafsson et al. 2012, Metzelthin et al. 2015). The professional most commonly delivering the intervention was a nurse, with 19 studies reporting this, usually a nurse with special training (Table 5). A single professional (varied professions: nurse, occupational therapist, physiotherapist, social worker, care manager or psychologist) was reported as the deliverer of the intervention in eight studies (Behm et al. 2016, Byles et al. 2004, Fabacher et al. 1994, Granbom et al. 2017, Gustafsson et al. 2012, Kono et al. 2012, Kono et al. 2016, Sahlen et al.

2006). Trained medical students were reported as the deliverers of the intervention in one study (Frese et al. 2012) and one study reported health visitors having delivered the intervention (Pathy et al. 1992). However, both of these studies were of low methodological quality.

The intensity of intervention varied in the PHV studies. The length of intervention and follow-up was from three months (Brettschneider et al. 2015, Crawford Shearer et al. 2010, Melis et al. 2008) to 48 months (Gunner-Svensson et al. 1984). The number of visits varied in the studies from one to two (Behm et al. 2016, Bleijenberg et al. 2016, Byles et al. 2004, Dalby et al. 2000, McEvan et al. 1990, Gunner-Svensson et al. 1984, Gustafsson et al. 2012, Kono et al. 2012, Metzelthin et al. 2015, Vetter et al. 1984) to 10–12 and more during a year (Fairhall et al. 2015, Granbom et al. 2017, Hebert et al. 2001). A tailored intervention programme was used in 16 of the included trials (Bleijenberg et al. 2016, Byles et al. 2004, Brettschneider et al. 2015, Dalby et al. 2000, Fabacher et al. 1994, Fairhall et al. 2015, Granbom et al. 2017, Gunner-Svensson et al. 1984, Hendriksen et al. 1984, Imhof et al. 2012, Metzelthin et al. 2015, Ploeg et al. 2010, Sahlen et al. 2006, Schraeder et al. 2001, Shapiro et al. 2002, van Hout et al. 2010), and 14 of the trials reported support to the intervention-group participants during follow-up, most commonly in the form of follow-up phone calls (Bouman et al. 2008a, Byles et al. 2004, Brettschneider et al. 2015, Dalby et al. 2000, Fabacher et al. 1994, Gunner-Svensson et al. 1984, Hendriksen et al. 1984, Imhof et al. 2012, Ploeg et al. 2010, Sahlen et al. 2006, Schraeder et al. 2001, Shapiro et al. 2002, Stuck et al. 1995, van Hout et al. 2010).

The outcome measures used in the studies were varied. In most studies, several outcome measures were reported. Of the studies included in the literature review, 26 reported the effects of PHVs on functioning or frailty (Tables 5, 9 and 10), 19 reported the effects of PHVs on well-being and QOL (Tables 5, 9 and 10), 27 studies reported outcomes on some variables related to healthcare and social services use or costs (Tables 5, 9 and 10), and 20 reported effects of the intervention on mortality (Tables 5, 9 and 10). The outcome measures used in the included trials are described in more detail in the literature-review section of this dissertation and in Table 5.

The important characteristics of the good- and moderate-quality studies having a potential impact on the effectiveness of the trial are summarized in Tables 9 and 10.

Table 9. Summary of the trial characteristics and findings in high-quality RCTs on PHVs among older people.

Study	Effectiveness on HRQoL and well-being	Effectiveness on functioning	Effectiveness on mortality	Effectiveness on use and costs of services	Stability of effects at follow-up	Mean age of participants	Decline in function as inclusion criterion	Home visits per year	Duration of intervention in months	Multiprofessional intervention
High-quality trials										
Behm et al. 2016		0/+			No	86	No	1	12	Yes/No
Bleijenberg et al. 2016	0	+	0	0	Yes	74	Yes	≥1	12	No
Bouman et al. 2008a	0	0	0			76	No	8	18	No
Brettschneider et al. 2015	0	0	+	0		85	No	3	3	Yes
Byles et al. 2004	+		0	0/-	Yes		No	1-2	36	Yes
Crawford Shearer et al. 2010	0/+				No		No	6	3	No
Fairhall et al. 2015	0	+	0	0/+	Yes	83	Yes	10+	12	Yes
Granbom et al. 2017		0/+			No	81	Yes	12	12	No
Gustafsson et al. 2012		0/+			Yes	86	No	1	12	Yes/No
Imhof et al. 2012	0	0/+	0	0/+	Yes	85	No	4	9	No
Kono et al. 2012, 2013		0/+		0	Yes	80	Yes	2	24	No
Kono et al. 2016		+		0/-	Yes	79	Yes	4	24	No
Melis et al. 2008	+	+		0/+		82	Yes	6	3	No
Metzelthin et al. 2015	0	0		0/-	No	77	Yes	2	6	Yes/No
Ploeg et al. 2010	0	0	0	0		81	Yes	3	12	No
Stuck et al. 1995		+		0/+	Yes	81	No	4	36	No
van Hout et al. 2010	0	0	0	0		81	Yes	≤4	18	No
van Rossum et al. 1993	0	0	0	0/+	Yes	c.78	No	≥4	36	No
Yamada et al. 2003	0/+					79	Yes	6	18	No

RCT, randomized controlled trial; PHV, preventive home visit; ≥, at least and according to individual needs; ≤, at most, according to individual needs; +, significant effect in experimental group; 0/+, favourable effect in some outcome measures compared with controls; 0/-, unfavourable effect in some outcome measures compared with controls; 0, no difference between intervention and control groups.

Table 10. Summary of the findings and trial characteristics in moderate-quality RCTs on PHVs among older people.

Study	Effectiveness on HRQoL and well-being	Effectiveness on functioning	Effectiveness on mortality	Effectiveness on use and costs of services	Stability of effects at follow-up	Mean age of participants	Decline in function as inclusion criterion	Home visits per year	Duration of intervention in months	Multiprofessional intervention
Moderate-quality trials										
Dalby et al. 2000			0	0		79	Yes	≥1	14	No
McEvan et al. 1990	+	0	0	0			No	1-2	20	No
Fabacher et al. 1994		0/+	0	0	Yes	72	No	4	12	No
Gunner-Svensson et al. 1984				0	Yes	79	No	≥1	48	No
Hebert et al. 2001	0	0	0	0		80	Yes	≥1	12	No
Sahlen et al. 2006, 2008	0		+	0/+	No	80	No	2	24	No
Schraeder et al. 2001		+	+	0	No	76	Yes	4	24	No
Shapiro et al. 2002	+		+	+	Yes	77	Yes	≥4	18	No
Stuck et al. 2000		0/+	0	0/+	Yes	82	No	4	36	No
Vetter et al. 1984		0	0/+	0			No	1	24	No

RCT, randomized controlled trial; PHV, preventive home visit, ≥, at least and according to individual needs; ≤, at most, according to individual needs; +, significant effect in experimental group; 0/+, favourable effect in some outcome measures compared with controls; 0, no difference between intervention and control groups.

5.1.3 *Effects on functioning, HRQoL and well-being, mortality, and use and costs of healthcare and social services*

Of the RCTs, 25/33 reported some favourable effects of PHVs (Table 5), and 22 of these studies were of good or moderate quality (Tables 5, 9 and 10). Favourable effects on functioning represented the most common finding in 13 trials (Behm et al. 2016, Bleijenberg et al. 2016, Fabacher et al. 1994, Fairhall et al. 2015, Granbom et al. 2017, Gustafsson et al. 2012, Imhof et al. 2012, Kono et al. 2012, 2016, Melis et al. 2008, Schraeder et al. 2001, Stuck et al. 1995, 2000). Positive effects of PHVs on well-being and/or HRQoL were reported in seven studies (Byles et al. 2004, Crawford Shearer et al. 2010, Melis et al. 2008, McEvan et al. 1990, Pathy et al. 1992, Shapiro et al. 2002, Yamada et al. 2003). The risk of death was significantly lower in the intervention group in seven studies (Brettschneider et al. 2015, Hendriksen et al. 1984, Pathy et al.

1992, Sahlen et al. 2006, Schraeder et al. 2001, Shapiro et al. 2002, Vetter et al. 1984) and one study reported a better chance of staying in the community, meaning the probability of dying or admitted to a nursing home was lower among participants in the intervention group compared with the control group (Frese et al. 2012).

Overall, only a few studies revealed favourable effects on well-being and HRQoL. The effects were mostly detected in some dimension of well-being or QOL, and not the overall HRQoL. There was no clear relationship between favourable effects and intensity and duration of the intervention, or the deliverers of the intervention. Those older people with better functioning might be more likely to benefit from PHV intervention in respect of their well-being or HRQoL, but the relationship is unclear due to the small amount of studies with positive findings (Markle-Reid et al. 2006, Rubenstein et al. 2001, Stuck et al. 2002).

Most PHV interventions did not affect well-being or HRQoL. One reason might be the measures used. EQ-5D and SF-36/RAND-36 were most commonly used for measuring HRQoL, and in most of such studies no differences between groups in HRQoL were detected in follow-up. The measures used might not be sensitive enough to show a difference in change in populations of older people.

Favourable effects of PHVs on the use of healthcare and social services, and costs, were reported in ten studies (Fairhall et al. 2015, Hendriksen et al. 1984, Imhof et al. 2012, Kono et al. 2013, Melis et al. 2008, Sahlen et al. 2008, Shapiro et al. 2002, Stuck et al. 1995, 2000, van Rossum et al. 1993), and one study reported that intervention-group participants were more likely to stay in the community (not dying or institutionalized) compared with the control group (Frese et al. 2012). Of these studies, two were of poor methodological quality (Hendriksen et al. 1984, Frese et al. 2012). The intervention group was less likely to be institutionalized in three studies (Melis et al. 2008, Shapiro et al. 2002, Stuck et al. 1995), and less likely to be hospitalized in four (Imhof et al. 2012, Melis et al. 2008, Kono et al. 2013, van Rossum et al. 1993) compared with the control group.

None of the studies included in the literature review showed statistically significant differences in total healthcare and social services costs between the intervention and control groups. Cost-effectiveness was explored in five studies, three of which found the intervention to be cost-effective, with varied levels of willingness to pay (Fairhall et al. 2015, Melis et al. 2008, Stuck et al. 1995) and two found the intervention not to be cost-effective (Brettschneider et al. 2015, Metzelthin et al. 2015).

Of the studies reporting some favourable effects on functioning, HRQoL or well-being, or mortality, eight also reported costs (Fairhall et al. 2015, Kono et al. 2012, Kono et al. 2013, Kono et

al. 2016, Melis et al. 2008, Sahlen et al. 2006, Sahlen et al. 2008, Schraeder et al. 2001, Stuck et al. 1995, Stuck et al. 2000). None of these studies reported the total costs to be significantly higher for the intervention group; thus the favourable results in these studies were produced cost-neutrally.

Only five studies explored the cost-effectiveness of PHV interventions. Three of these found the intervention to be cost-effective (Fairhall et al. 2015, Melis et al. 2008, Stuck et al. 1995) and two reported the intervention not to be cost-effective (Brettschneider et al. 2015, Metzelthin et al. 2015). It is difficult to compare these studies with each other due to the variety of target groups, interventions and methods of evaluating cost-effectiveness.

Table 9 summarizes the findings in PHV studies rated as being of high quality and Table 10 summarizes the findings of the studies rated as being of moderate methodological quality.

5.2 Characteristics of the participants in the PHV intervention study (II–IV)

The mean age of the 422 participants was 81 years and 65% of the participants were female. The participants' mean level of education was 10 years of formal education. Slightly more than half of the participants were cohabiting. The participants were mostly satisfied with their lives and HRQoL on the 15D measure was similar at baseline in both groups. Functional performance in usual activities of the participants was good at baseline, with over 80% of participants being able to perform their usual activities without difficulty or with only minor difficulty.

There was no statistically significant difference between the groups in the Charlson comorbidity index. However, a slightly lower proportion of participants in the intervention group (n = 28, 13%) had a diabetes diagnosis compared with the control group (n = 46, 22%; $p = 0.02$). A slightly lower proportion of the participants in the intervention group used a walking aid than in the control group. However, there was no difference in mobility in 15D between the groups at baseline. There were no other significant differences between the groups at baseline, and HRQoL measured by means of the 15D instrument was similar between the groups at baseline. Table 11 describes the characteristics of the participants at baseline.

Persons of a similar age in the background population of Hyvinkää were slightly older (mean age 81.6 years), and the proportion of married older people in the background population was slightly lower (41% vs. 51%). The proportion of females (65%) was similar in the trial participants compared with that in the background population.

Table 11. Characteristics of the participants of the preventive home visit (PHV) trial and their use of healthcare and social services at baseline.

Characteristics	Intervention group (n = 211)	Control group (n = 211)	*p* value[6]
Age, mean (SD[1])	80.8 (4.3)	81.3 (4.3)	0.20
Females, n (%)	138 (65)	136 (65)	0.84
Cohabiting	110 (52)	105 (51)	0.70
Education, years (SD[1])	10.0 (3.9)	9.8 (3.7)	0.63
Satisfaction with life, n (%):			0.55
Satisfied	187 (90)	185 (89)	
Unsatisfied	11 (6)	12 (5)	
Cannot say	9 (4)	12 (6)	
HRQoL[2]: 15D[3] score (SD[1])	0.82 (0.11)	0.82 (0.11)	0.87
15D usual activities 1–2	173 (82)	172 (82)	0.90
Charlson comorbidity index[5] (SD[1])	1.3 (1.3)	1.4 (1.5)	0.61
BMI[4] (SD[1])	26.5 (5.0)	26.5 (4.9)	0.62
Smoking:			0.60
Current, n (%)	10 (5)	6 (3)	
Ex-smoker, n (%)	35 (17)	36 (17)	
Alcohol risk use, n (%)	17 (8)	15 (7)	0.71
Fallen during last 6 months, n (%)	68 (32)	54 (26)	0.14
Exercise ≥ 30 min at least once per week, n (%)	149 (71)	145 (71)	0.88
Uses a walking aid, n (%)	21 (10)	35 (17)	0.05
Prescription medications regularly taken (SD[1])	4.4 (2.6)	4.5 (2.9)	0.77
Primary care use (previous year), mean (SD)			
Nurse visits	2.31 (3.70)	2.57 (4.11)	0.52
General practitioner visits	1.93 (1.82)	1.89 (1.89)	0.83
Other specialists' visits	0.61 (1.87)	0.44 (1.09)	0.27
Primary-care ward days	1.00 (6.44)	1.18 (5.76)	0.77
Day-care days	0.47 (4.92)	1.42 (9.43)	0.21
Specialized medical care, mean (SD)			
Outpatient visits	1.13 (1.86)	1.12 (1.95)	0.98
Emergency department visits	0.69 (1.25)	0.63 (1.14)	0.63
Hospital ward care days	0.99 (3.18)	1.16 (5.03)	0.70

[1]SD = standard deviation; [2]HRQoL = health-related quality of life; [3]Sintonen 2001; [4]BMI = body mass index; [5]Charlson et al. 1987; [6]Differences between groups tested using χ^2 or Fisher's exact test for categorial variables and the Mann–Whitney *U* test or the permutation test for continuous variables.

Drop-outs who had no data on 15D in follow-up were older (mean age 83.1 years, SD 4.6) and with lower HRQoL (mean 15D score 0.76, SD 0.12) at baseline than those who completed the study. However, there were no differences between dropouts in intervention and control groups at baseline on 15D score, age and sex.

Data on use of healthcare and social services was retrieved for one year before the intervention to compare such use at baseline between the intervention and control groups. There were no significant differences in use of any of the collected healthcare and social services between the groups (Table 11).

5.3 Feasibility of multiprofessional PHV intervention (II)

The PHV intervention used in the trial was simple, and transferable to other primary-care settings. Although some of the home visits had to be postponed to a later date, for example due to an acute illness, the professionals reported that all the home visits were carried out as planned. The professionals reported the implementation of structured assessments and instructed and planned interventions, and these were implemented as instructed. During their visits, the physiotherapist and social worker checked whether the participant had understood the instructions left by the prior visitor and the extent to which the participants had followed the instructions. The participants had mostly followed the instructions well.

The short questionnaire used for evaluation of participant satisfaction with PHV intervention at the 1-year follow-up time-point is described in Methods (section 4.4). The participants who received the home visits gave mostly favourable feedback. The response rate was good, with 81% of the intervention group returning the questionnaire. Of those who answered, 70% stated they received new information on available services, and 59% wished to receive home visits in future if there would be an opportunity. Only 13% did not find the home visits beneficial and 9% would not have wished for further home visits. However, 59% stated that their health or functioning had not improved after the home visits and 58% stated that their well-being had not improved. Health, functioning and well-being of the participants were likely to deteriorate during this one-year period, considering their age; thus this questionnaire was not a good measure for these variables. Table 12 describes the participants' responses in more detail.

Table 12. Answers to feedback survey on the home visits. Reproduced with permission from European Geriatric Medicine.

Question	Yes n (%)	No n (%)	Could not say n (%)
Did you find the home visits beneficial?	66 (40)	21 (13)	79 (48)
Did you get new information about available services?	118 (70)	21 (12)	30 (18)
Did you receive new information on supporting or improving your health?	73 (44)	47 (28)	46 (28)
Has your health or functioning improved due to the home visits?	8 (5)	101 (59)	61 (36)
Has your well-being increased?	17 (10)	96 (58)	54 (32)
Do you wish to receive similar home visits in the future if there is an opportunity?	98 (59)	15 (9)	52 (32)

5.4 Effects of PHV intervention targeted to home-dwelling older people (III, IV)

5.4.1 *Effects of PHV intervention on HRQoL and mortality in home-dwelling older people (III, IV)*

In the intervention group compared with the control group, HRQoL (15D score) declined significantly more slowly over time (p for group 0.18, for time < 0.001 and for group#time 0.043 adjusted for age and sex). The difference in changes between groups in the 15D score was -0.015 (95% CI -0.029 to -0.0016; $p = 0.028$ adjusted for age, sex, and baseline value) measured at the one-year follow-up. However, the effect became diluted once the visits ended, the difference between groups (-0.0093) being no longer significant (95% CI -0.031 to 0.013; $p = 0.41$ adjusted for age, sex, and baseline value; Figure 3) at the two-year follow-up.

The dimensions of the 15D score showed favourable differences stemming from sleeping, mental functioning, discomfort/symptoms, and vitality at the one-year follow-up. However, the differences in these individual areas of 15D did not reach significance when adjusted for age, sex and baseline values (Figure 4).

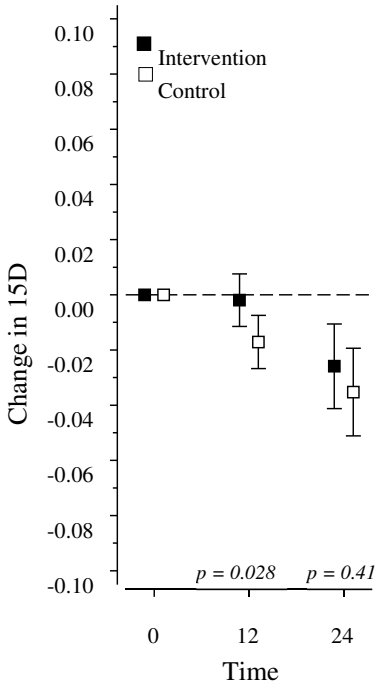

Figure 3. Effects (mean with 95% confidence interval shown as point estimate and whiskers) of the intervention on the change in health-related quality of life on a 15D scale (adjusted for age, sex and baseline) at one-year and two-year follow-up points. Reproduced with permission from the Scandinavian Journal of Primary Health Care.

Of the participants, 13 died during the two-year follow-up: five in the intervention group and eight in the control group. There was no significant difference in mortality between the groups. The hazard ratio in the control group was 2.4 (95% CI 0.7 to 9.1, $p = 0.19$ adjusted for age, sex, and the Charlson comorbidity index) in Cox regression analysis.

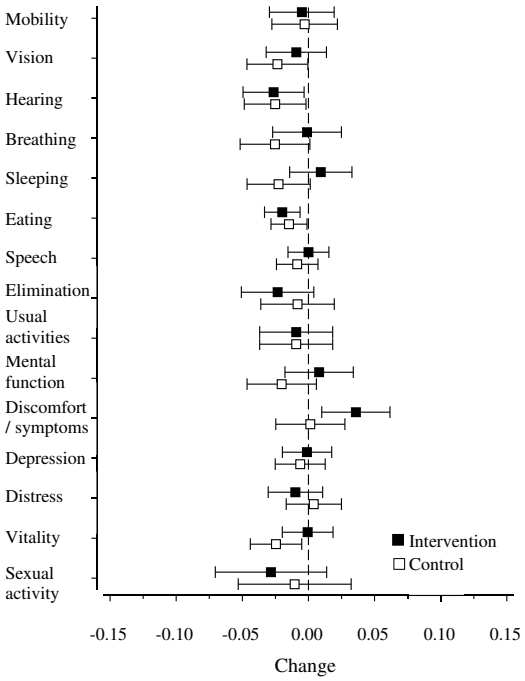

Figure 4. Effects of the intervention on the dimensions of a 15D scale at the one-year follow-up. Reproduced with permission from the Scandinavian Journal of Primary Health Care.

Although HRQoL (15D measure) had declined significantly more slowly at the one-year follow-up, there was no significant difference in QALYs between the intervention and control groups during two-year follow-up. In the intervention group the mean for QALYs was 0.819 (SD 0.112) whereas the respective figure in the control group was 0.812 (SD 0.114). The difference in QALYs between the groups was -0.007 (95% CI -0.029 to 0.015; $p = 0.52$). After performing an imputation the difference between the groups was -0.005 (95% CI -0.035 to 0.022; p=0.48).

5.4.2 *Effects of PHV intervention on use and costs of services and cost-effectiveness of PHV intervention (IV)*

The participants' mean use and costs of healthcare and social services per person-year during the two-year follow-up were analysed in the intervention and control groups (Table 13). In the intervention group the mean total cost per person-year in the 24-month follow-up was 6929€ (SE 846) and in the control group the respective figure was 8277€ (SE 1089). There was no significant difference between the intervention and control groups in total costs (mean difference -1349€ [-4119€ to 1172€]). The median total costs per person years in the 24-month follow-up were 1848€ (IQR: 837 , 7341) in the intervention group and 2485€ (IQR: 1049 , 7231) in the control group (median difference -258€ [-711€ to 157€]). The cost of the intervention was 382€ per participant. The findings did not change when the intervention costs were included in the total costs for the intervention group, the mean total cost per person at two-year follow-up then being 7310€ (SE 849). When including the intervention costs the mean difference between groups was -967€ (-3766 to 1633) (mean ratio 0.84 [0.55 to 1.13]).

Table 13. Use and Costs of Health and Social Services during the 24-month Follow-up in Person-years (pyrs)

	Mean use of healthcare (pyrs)		Mean costs of healthcare (€, pyrs)		
	Intervention (n = 211) Mean (SE[1])	Control (n = 211) Mean (SE[1])	Intervention (n = 211) Mean (SE[1])	Control (n = 211) Mean (SE[1])	Mean difference in costs (95% CI)[2]
Primary care					
Nurse consultations	2.28 (0.17)	2.37 (0.19)	229 (17)	237 (19)	-8 (-61 to 43)
General practitioner consultations	2.04 (0.11)	1.95 (0.11)	474 (26)	449 (25)	25 (-41 to 99)
Other specialists' consultations[3]	0.59 (0.07)	0.67 (0.07)	94 (11)	104 (11)	-10 (-40 to 21)
Homecare visits	6.73 (1.93)	11.81 (4.26)	596 (175)	1028 (374)	-433 (-1459 to 183)
Primary-care ward days	3.58 (0.89)	4.34 (0.97)	1572 (384)	1766 (373)	-194 (-1224 to 904)
Day-care days	0.57 (0.22)	1.05 (0.38)	117 (47)	200 (73)	-83 (-286 to 61)
Respite-care days	0.19 (0.12)	0.00 (0.00)	68 (40)	0 (0)	68 (-17 to 217)
Specialized medical care					
Outpatient visits	0.94 (0.10)	1.26 (0.12)	518 (52)	673 (63)	-155 (-324 to 3)
Emergency-department visits	0.79 (0.08)	0.85 (0.08)	464 (45)	469 (42)	-6 (-119 to 117)
Hospital-ward care days	1.61 (0.23)	2.10 (0.35)	2488 (356)	2973 (508)	-485 (-1871 to 607)
Nursing-home days	1.11 (0.74)	1.36 (1.25)	309 (208)	378 (344)	-70 (-1340 to 479)
Total			6929 (846)	8277 (1089)	-1349 (-4119 to 1172)
Intervention costs			382	..	
Total including intervention			7310 (849)	8277 (1089)	-967 (-3766 to 1633)

[1]Bootstrap-type standard error (SE) of the mean.

[2]The 95% confidence intervals were obtained by bias-corrected bootstrapping (10,000 replications).

[3]Other = other services including physiotherapist, occupational therapist, speech therapist, nutritionist, social worker and foot-care specialist.

As there was a significant difference in the change of HRQoL between the groups, a bootstrap analysis was performed concerning QALYs in cost-utility analysis although there were no significant differences in QALYs gained. The bootstrap analysis helps to manage the uncertainty around point-estimates of ICERs and the plotting on cost-effectiveness plane reflects the variability within the original study sample. The cost-effectiveness plane in this cost-utility analysis shows 60% of the ICERs lying in the dominant ("south east") quadrant (Figure 5), which represents the probability of the intervention having more effect and lower costs compared with usual care.

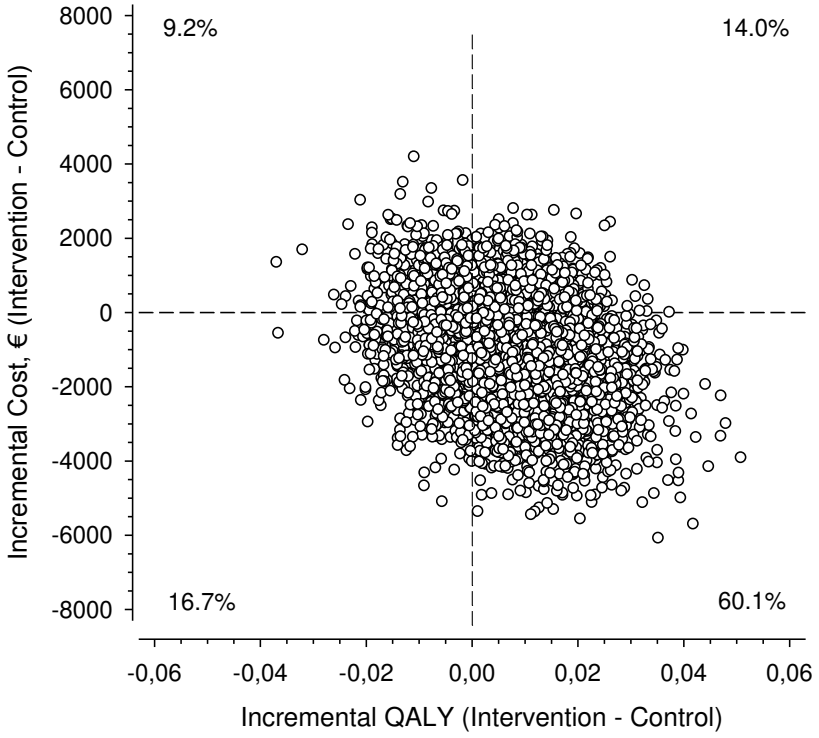

Figure 5. Incremental cost-effectiveness planes for costs and health-related quality of life outcomes of 5000 bootstrapped replicates. The percentages in the four quadrants denote the estimates that fell within each quadrant: 9.2% more costly, less effect on QALY, 14.0% more costly, more effect on QALY, 60.1% less costly, more effect on QALY and 16.7% less costly, less effect on QALY. Reproduced with permission from the The Journals of Gerontology, Series A, Medical Sciences, published in 2019 (10.1093/gerona/glz139).

5.5 Adverse effects of multiprofessional PHV intervention (II–IV)

In the PHV intervention trial (Studies II–IV), no adverse events were recorded during the intervention. There were no drop-outs during the home-visit intervention, all visits were performed as planned, and compliance was mostly good. There were no significant differences in services use between the groups, and services use did not significantly increase in the intervention group compared with the control group in the follow-up (Table 13).

6 Discussion

The systematic review exploring the effectiveness of PHV interventions targeted to older people suggested that these interventions have some favourable effects on functioning, HRQoL and well-being, and mortality. A few of the studies included in the review suggested favourable effects on the rates of institutionalization and hospitalization, but most of the studies did not reveal any effects on these. None of the studies showed significant differences between intervention and control groups in total costs of care. Those studies that reported favourable findings in functioning, HRQoL and well-being, or mortality, and reported costs of services use by the participants, suggested that the favourable findings were achieved cost-neutrally.

Findings in the PHV intervention study, an RCT examining the effects of multiprofessional PHV intervention on the HRQoL of home-dwelling older people, suggested significant favourable effects on HRQoL measured on the 15D scale during the one-year follow-up. However, the effects were diluted at two-year follow-up, and were no longer significant between the intervention and control groups. No significant differences in QALYs gained, on use of healthcare and social services, nor total costs were shown between the groups. However, cost-utility analysis showed that the majority (60%) of ICERs fell in the dominant ("south east") quadrant, suggesting that the intervention might be effective, with lower costs. As there was no significant difference between groups in the total costs, the effects of the intervention were seen to have been achieved cost-neutrally.

6.1 Methodological considerations

The systematic literature review was conducted on RCTs, and the PHV intervention trial was conducted as an RCT. The most reliable evidence on the efficacy of an intervention is considered to be provided by RCT studies. The risks of bias are minimized by random allocation of patients. However, the quality of RCTs has to be evaluated before their reliability and relevance in care are considered (Guyatt et al. 1993). Unless the RCT has a methodologically appropriate study design, with good implementation, analysis and reporting, aiming to prevent systematic errors, it cannot produce reliable data. When considering RCT studies exploring complex multifactorial interventions, the possibility of biased external validity has to be kept in mind, as in an RCT setting the circumstances might be more controlled than in actual practice (Elkan et al. 2001).

The review concerned published information, which might be a source of bias, as positive results are published more often. However, the present literature review included several studies with only

a small or no clinical effect, which would suggest that null results in PVH intervention studies are also published.

The heterogeneity of RCTs exploring the effects of PHV interventions is a challenge when comparing their results. Although the definition of PHV trials used in the present literature review was fairly narrow compared with some (Mayo-Wilson et al. 2014), the participants included in the trials, intervention components and intensity, and outcomes reported were varied. Thus, the possibly poor comparability of the studies needs to be remembered when interpreting the results. The challenge when comparing PHV studies in terms of their effectiveness has been discussed in earlier reviews (Beswick et al. 2008, Lin et al. 2012, van Haastregt et al. 2000). Due to the heterogeneity of the studies, a meta-analysis was not conducted as part of the present literature review. It has been stated that meta-analyses might not reliably show the effectiveness of PHV studies due to the heterogeneity of outcomes used and that of the populations of older people included in the studies, and variability in the health trajectories of older people (Lin et al. 2012).

In the systematic review we used the PRISMA checklist (Moher et al. 2009) and thus rigorous methodology was employed. The systematic review fulfilled following methodological checklist items for reviews with no meta-analysis: study eligibility criteria described, information sources and search strategy described, study selection, data collection and data items defined, risk of bias of individual studies evaluated, and risk of bias across studies evaluated. The review did not state a separate review protocol and where it could be accessed, nor registration information.

The present PHV intervention study was based on careful planning and a rigorous RCT setting. It included few exclusion criteria, thus including participants fairly representative of the background population of home-dwelling older people. The participants were independent home-dwelling people aged 75 years or more, receiving no regular home care and living in Hyvinkää municipality in Finland. Those in a respective age group in the background population were slightly older and more often single than the participants in the present PHV trial. People living in institutions and receiving regular home care are more likely to be older and single than those who fulfilled the inclusion criteria of the present PHV trial, which explains the differences between the participants and the background Hyvinkää population.

The PHV intervention of three home visits by professionals was designed to be practicable and transferrable to other primary-care contexts. CGA was implemented in the intervention, which has been proven to be effective in assessment and treatment of older people (Lundqvist et al. 2018, Panza et al. 2018, Stuck et al. 2002). The home visits were semi-structured, with professionals

having received thorough training and instructions for implementation of the intervention. Validated measures were used for CGA assessment during the intervention. The intervention and further plans were individualized according to the needs and wishes of the participant.

The randomization of the 422 participants into intervention and control groups appeared to be successful, and the groups were balanced at baseline. Spouses were randomized together to avoid contamination of the intervention effect. Compliance was good in the intervention group. Barriers to participating were low, as the professionals visited the older people's homes and the home visit date could be changed if any barriers arose concerning the suggested date. All of the home visits were delivered according to plan, and there were no drop-outs in the intervention group during the intervention period. The PHV intervention was well received by the participants in the intervention group, with only 9% not wishing for further home visits.

The control group did not receive any active intervention. They continued treatment as usual and were entitled to all the normal services for older people that the municipality offered. They could, for example, contact their GP or community nurse, have service needs assessment or see a physiotherapist if needed during the study period. The services offered to older people in Finland are in general of high quality, and this may have diluted the differences between the groups. The participants in the intervention group were not restricted in contacting the services the municipality offered or other healthcare and social-service providers if needed. In addition, the control group received and answered the same postal questionnaires as the intervention group. This may have also diluted the differences between the groups. Data on use of healthcare and social services were retrieved for both the intervention and control groups for the duration of the two-year follow up as part of the trial. However, there were no significant differences in the use of services between the intervention and control groups, which supports the hypothesis that favourable results achieved were due to the intervention.

The primary outcome in the PHV trial was HRQoL (15D measure) (Sintonen 2001), which is a patient-relevant outcome measure. The 15D measure is self-reported and can be obtained by using a postal questionnaire. It has shown a good validity in older populations, and it is sensitive to changes after intervention (Alanne et al. 2015, Pitkala et al. 2009, Pitkala et al. 2014, Strandberg et al. 2006). Of the total study population 11% (22 intervention participants and 26 control participants) did not have 15D information during the follow-up. The drop-out rate was low for a study targeting older people (ref). Although drop-outs were older and had lower baseline HRQoL than those who completed the study, there were no differences between intervention and control groups in baseline

15D score, age and sex of the dropouts. Therefore, it is unlikely that the drop-outs would have influenced the outcome of the study.

Secondary outcomes of the PHV trial were mortality and use and costs of healthcare and social services. There was no significant difference between the groups in mortality. The participants were fairly healthy older people, and the mortality rate of the participants during the trial was low. Most likely the study lacked the power to detect differences in mortality.

The data on use and costs of healthcare and social services were collected one year before the intervention (baseline measures) and during two years of follow-up. The groups were balanced in their use of services at baseline. The costs of intervention were calculated on the basis of mean unit costs for healthcare and social services in Finland in 2011 (Kapiainen et al. 2011) with appropriate correction for the inflation rate added to the costs. The recording of use of services in Finnish medical records and central registers is reliable, so it is unlikely that any significant services-use data were missed.

QALYs were used for the cost-utility analysis. As there was missing data on 15D due to drop-outs during follow-up, this missing data could have created bias in the results of the cost-utility analysis on QALYs and cost-effectiveness plane ICER plotting. An analysis with using multiple imputation by chained equations (10 datasets) was run and the results were similar to the original QALY analyses. Therefore, the chance of bias on cost-effectiveness analysis due to drop-outs is small.

6.2 Methodology and characteristics of previous PHV trials

In the systematic review, the methodological quality of the included RCTs was mostly good, with 19 out of 33 studies being of good quality. Only four of the studies included were of poor methodological quality. In earlier reviews PHV trials have been criticised for insufficient reporting of trial drop-outs, outcomes, and components of the interventions (Lin et al. 2012, Mayo-Wilson et al. 2014, van Haastregt et al. 2000). Many trials have also been found lacking in reporting of the treatment received by the control group and whether or not it was comparable between the studies, and in reporting the compliance of the participants (Bouman et al. 2008a, Mayo-Wilson et al. 2014, van Haastregt et al. 2000). The most typical methodological weaknesses in the studies included in the present review were associated with lack of information on blinding the group assignment when assessing the outcomes, and inadequate description of randomization methods. Furthermore, several investigators described the trial drop-outs inadequately or did not conduct an ITT analysis, or the studies lacked a power calculation or had low statistical power. However, most publications

sufficiently described the intervention, and inclusion and exclusion criteria, the outcome measures were mostly valid, and the groups were mostly appropriately compared in relation to the outcome measures.

The variety of settings in which the RCTs were performed proves a challenge both in comparing the results of the studies and in generalizability to other settings and groups of older people. In studies of preventive, multifactorial interventions such as PHVs, differences in settings and usual care offered to the general older population might affect the results (Beswick et al. 2008, Mayo-Wilson et al. 2014). In addition, healthcare and social services offered by societies have developed greatly in the past few decades, proving a challenge in comparing results of older and newer studies. Furthermore, RCTs may be subject to selection bias, as the participants of intervention studies are often motivated and more active than non-participants, which might affect the generalizability of the results to other groups of older people (Martinson et al. 2010). However, most of the RCTs included in the present literature review presented fairly few exclusion criteria, and the intervention protocols were mostly designed to be practicable, which would support good transferability of the interventions to other primary-care settings and populations of older people.

As stated in earlier reviews, there were not many common characteristics among the studies showing beneficial findings. However, the intensity of the intervention and sufficient follow-up with support might be features that increase the probability of favourable results, which is in line with earlier literature (Stuck et al. 2002). The intensity of the intervention seems to be associated with favourable findings on use and costs of services (Fairhall et al. 2015, Imhof et al. 2012, Melis et al. 2008, Shapiro et al. 2002, Stuck et al. 2000, Stuck et al. 1995, van Rossum et al. 1993). In studies with a relatively long follow-up but no support for the intervention group after initial intervention, the favourable effects became diluted during the follow-up period (Behm et al. 2016, Crawford Shearer et al. 2010, Sahlen et al. 2006, Schraeder et al. 2001). In addition, relatively well functioning older people aged 80 years or more might be more likely to benefit than those with poor functional status or those who are younger. This might be a result of ceiling and floor effects. With a relatively young population of older people, the effects of intervention might not show, as most of them are relatively fit and not at risk of functional disabilities or poor health outcomes. On the other hand, among those who already have functional disabilities, PHV interventions might not be able to create effects of an intensity that would show between groups.

6.3 Effects of PHV interventions on functioning, HRQoL and well-being, and mortality of older people

Of the RCTs exploring the effects of PHV interventions targeted to home-dwelling older people, 22 out of 33 revealed some favourable effects: 15 on functioning, seven on well-being and/or HRQoL, and seven on mortality. The effects, although significant, were mainly modest, and in three studies the favourable effects were restricted to a predetermined subgroup of participants (Kono et al. 2012, Vetter et al. 1984, Yamada et al. 2003). These findings are in line with those in several earlier reviews (Beswick et al. 2008, Elkan et al. 2001, Huss et al. 2008, Markle-Reid et al. 2006, Stuck et al. 2002, Toljamo et al. 2005). When a fairly unselected population of older people with different health trajectories is being targeted with multifactorial intervention to support general functioning, well-being or health, some might benefit considerably, some only modestly and some might not gain any benefit from the intervention (Lin et al. 2012). This heterogeneity in the effects of intervention among participants might be one factor explaining the modest findings.

An earlier large review on various PHV interventions showed less favourable findings (Mayo-Wilson et al. 2014). However, the inclusion of a large amount of studies targeted to different populations, with various interventions and outcomes measured and reported might have diluted the results. It has been proposed that meta-analyses suggesting minor or no effects might not mean that multifactorial interventions in PHV studies are ineffective. Minor effects might reflect the fact that some older adults gain substantial benefits whereas many might not gain any, when the variety of outcomes used to measure effects in heterogeneous populations of older people are considered (Lin et al. 2012).

Of the RCTs exploring the effects of PHV interventions, 14 were performed on subjects with a decline in functioning or at risk of such a decline. In RCTs exploring the effects of PHVs, there were no major differences in the effectiveness of PHV interventions targeted to populations with functional decline or risk of it, and those which were targeted to populations with unselected functional ability. Earlier reviews have suggested that persons with relatively good functional status might benefit the most from PHV interventions (Stuck et al. 2002, Toljamo et al. 2005). It has been discussed that preventive programmes for older people might lead to poor participation and loss of cost-effectiveness if they are not properly targeted (Ford et al. 2017). Defining the best target group for PHV interventions is problematic, as most reviews have not pinpointed participant characteristics which would distinguish those older people who would benefit the most from PHV

interventions from those to whom the visits might not be beneficial (Beswick et al. 2008, Elkan et al. 2001, Huss et al. 2008, Lin et al. 2012).

In the RCTs included, no components of the PHV interventions appeared to distinguish programmes with favourable effects on functioning, well-being and HRQoL, and mortality from ineffective programmes. This is in line with the results of earlier reviews which suggest that PHV interventions of various designs can produce favourable effects (Beswick et al. 2008, Fagerström et al. 2009). It has been discussed that it might not be possible to separate which parts of the intervention are the effective elements when studying complex multifactorial interventions targeting older people (Beswick et al. 2008, Lin et al. 2012, Walker et al. 2017). Current research suggests that individualized and tailored interventions implementing CGA might have most potential in assessment, prevention, and health promotion targeted to older people (Beswick et al. 2008, Fagerström et al. 2009, Stuck et al. 2002).

In the present RCT concerning multiprofessional PHV intervention, HRQoL (15D measure) in the intervention group declined more slowly than in the control group. HRQoL tends to deteriorate over time in older people (Fairhall et al. 2015, Kono et al. 2012, Shapiro et al. 2002). Thus, the PHV intervention was aimed at slowing down this deterioration. The positive effect was small but considered clinically significant (Alanne et al. 2015). The effect became diluted when the intervention was discontinued, and it was no longer significant at the two-year follow-up, which is in line with the results of several earlier studies (Behm et al. 2016, Sahlen et al. 2006, Schraeder et al. 2001, Stuck et al. 2002). The intervention did not include any support for the intervention-group participants during the follow-up period after the three initial home visits, and other studies have also shown dilution of favourable clinical effects of an intervention when lacking such support (Behm et al. 2016, Stuck et al. 2002).

Only one of the included RCTs revealed a favourable effect on HRQoL (Yamada et al. 2003). Some studies have shown positive effects of home-visit interventions on well-being or dimensions of HRQoL of older people (Byles et al. 2004, Counsell et al. 2007, Pathy et al. 1992, Shapiro et al. 2002), findings that the present trial confirm. However, in contrast to findings in the present RCT, many of the earlier trials failed to show significant favourable effects on HRQoL (Bleijenberg et al. 2016, Bouman et al. 2008a, Brettschneider et al. 2015, Fairhall et al. 2015, Hebert et al. 2001, Imhof et al. 2012, Metzelthin et al. 2015, Ploeg et al. 2010, van Hout et al. 2010). A large review revealed only low-quality evidence of effects of PHVs on QOL (Mayo-Wilson et al. 2014). None of

the trials we looked at showed adverse effects of the intervention on functioning, HRQoL or well-being of the participants.

In the present RCT, showing favourable effects on HRQoL, there were no inclusion or exclusion criteria based on functioning, and the participants had fairly good functional status at baseline. Many of the RCTs which did not show effects on HRQoL were performed on participants with a decline in functioning (Bleijenberg et al. 2016, Fairhall et al. 2015, Hebert et al. 2001, Metzelthin et al. 2015, Ploeg et al. 2010, van Hout et al. 2010). The participants in these studies might not have gained as much from the preventive intervention as participants with better functional status. Preventive interventions work best at early and reversible stages of disabilities and illnesses and participants with poor functional status might require more intensive intervention for any effects to show (Markle-Reid et al. 2006, Rubenstein et al. 2001). These findings are in line with those in earlier reviews suggesting that fairly well functioning older people benefit most from PHVs (Stuck et al. 2002, Toljamo et al. 2005).

The null findings of some studies on the effects of PHV interventions on HRQoL of older people might be partly a result of the used HRQoL measures not being able to show a difference in change between groups in the study populations. The 15D measure has shown good validity in older populations and sensitivity to change in earlier studies (Kattainen et al. 2005, Pitkala et al. 2014, Strandberg et al. 2006). When studying intervention effects on HRQoL in populations of older people, the use of instruments that have been proven valid in older populations is of importance (Cummins 1997, Guyatt 2007). In an earlier review it was noted that the instruments used for assessing outcomes in PHV studies might not be sensitive enough to detect modest improvements in health or functional ability (Elkan et al. 2001).

The present RCT did not show significant differences in mortality between the groups. The power of the trial might not have been large enough to show differences in mortality in a sample of fairly healthy older people. This finding on the effect on mortality is largely in line with the results of earlier studies. Although some of the earlier studies have shown PHVs to reduce mortality (Hendriksen et al. 1984, Pathy et al. 1992, Sahlen et al. 2006, Schraeder et al. 2001, Shapiro et al. 2002, Vetter et al. 1984), most studies have not shown differences in mortality between the intervention and control groups. The more recent studies may have been unable to show favourable effects on mortality as nowadays the healthcare and social services offered to older people are likely to be more comprehensive.

There was no significant difference in QALYs gained between the intervention and control groups in the present RCT. Various factors might explain this. Firstly, no difference in mortality between groups was detected. Secondly, although the effect of the intervention on HRQoL was favourable, it was relatively modest and the effect diluted at the second year of follow-up.

The results of the present trial on QALYs are in line with those in earlier RCTs exploring the effects of PHVs on QALYs, most of which showed no differences between groups (Brettschneider et al. 2015, Fairhall et al. 2015, Metzelthin et al. 2015, Ploeg et al. 2010). Only one trial showed higher QALYs gained in the intervention group compared with the control group (Sahlen et al. 2008). The gained QALYs stemmed mainly from gained life years, as the mortality rate in the intervention group vs. the controls was lower. No significant difference in HRQoL was reported (Sahlen et al. 2008).

The uses of QALYs are limited when evaluating interventions aimed at promoting older peoples' health (Edlin 2014, Huter et al. 2016). Instruments used to assess QOL in intervention studies might not be sensitive enough in older populations and the measures used to calculate QALYs are usually limited to HRQoL. These might not capture non-health-focused effects important to older individuals, such as social effects or supported independence (Frytak 2000, Thompson et al. 2012, Vaarama 2009). Even healthy older people have a lower remaining life expectancy, which lowers the possible gain in life years, and in QALYs gained, compared with that of younger people. As most older people have comorbidities, the health gains according to HRQoL measures are often small and there is a risk of a floor effect (Melis et al. 2008). Thus, interventions targeting older people might lead to less improvement in QOL and smaller or non-significant differences between groups in QALYs gained, compared with interventions targeting younger populations (Edlin 2014, Huter et al. 2016, Melis et al. 2008).

6.4 Effects of PHV interventions on use and costs of healthcare and social services, and their cost-effectiveness

Of the RCTs exploring PHVs, 10 of 33 reported some favourable effects of intervention on healthcare and social services use and costs (Fairhall et al. 2015, Hendriksen et al. 1984, Imhof et al. 2012, Kono et al. 2013, Melis et al. 2008, Sahlen et al. 2008, Shapiro et al. 2002, Stuck et al. 1995, Stuck et al. 2000, van Rossum et al. 1993). The most often reported effects were lower rates of institutionalization and/or hospitalization. The favourable findings were mostly modest. These findings are in line with those in earlier reviews, which have suggested PHVs to have modest to no

effects on the use of healthcare and social services, with the favourable effects mostly stemming from less institutionalization in the intervention group (Beswick et al. 2008, Elkan et al. 2001, Markle-Reid et al. 2006, Mayo-Wilson et al. 2014, Toljamo et al. 2005). None of the studies showed differences between intervention and control groups in total costs of healthcare and social services.

The conclusions of two earlier reviews on the cost-effectiveness of PHVs were in line with the results of Study I. In both of the earlier systematic reviews it was stated that there is a lack of research on the cost-effectiveness of PHV interventions (Corrieri et al. 2011, Tappenden et al. 2012). These reviews were performed on a narrower selection of trials compared with the present systematic review (I), one focusing on PHV intervention studies performed in Great Britain (Tappenden et al. 2012) and one focusing on fall-prevention trials (Corrieri et al. 2011). Only a few PHV trials (n = 5) have explored the cost-effectiveness of PHV interventions. It remains difficult to identify which elements of PHV trials might lead to cost-effective results (Corrieri et al. 2011, Tappenden et al. 2012).

In the trials included in the systematic review (I), some reported more use of primary care, home care and social services in the intervention group compared with the control group (Hendriksen et al. 1984, Stuck et al.1995, Stuck et al. 2000, Vetter et al. 1984). However, the same studies revealed lower rates of institutionalization and mortality in the intervention group (Hendriksen et al. 1984, Stuck et al.1995, Stuck et al. 2000, Vetter et al. 1984). Thus, the increase in use of less resource-intensive healthcare and social services in the intervention group could be seen as a neutral or desired effect of the intervention rather than an adverse effect. Only one trial showed more nursing-home admissions in the intervention group compared with the control group (Byles et al. 2004). In one trial higher healthcare costs in the intervention group compared with controls were reported (Metzelthin et al. 2015), but in this trial the participants in the intervention group had more disabilities and were more likely to be frail at baseline compared with the controls.

The results in the systematic review exploring RCTs are similar to those in earlier reviews on the effectiveness of PHVs on use and costs of healthcare and social services. Some studies have suggested favourable findings, but the findings remain modest. When comparing the studies, older people (80 years old or more) with relatively good functional status seem to benefit the most when focusing on PHV intervention effects on healthcare use and costs. The strongest association seems to be with the intensity of the intervention, with PHV programmes of four home visits or more being more likely to produce favourable outcomes. Some studies have indicated that

multiprofessional PHV interventions implementing structured CGA and with sufficient follow-up visits would be more likely to produce favourable results on the use of costly services such as institutionalization (Stuck et al. 2002). However, earlier reviews have shown only modest and non-significant effects, if any, of PHV interventions on rates of institutionalization and hospitalization (Bouman et al. 2008a, Huss et al. 2008, Mayo-Wilson et al. 2014, Stuck et al. 2002). The cost-effectiveness of PHV interventions remains unclear, with only a few studies having explored it, none showing significant differences in total costs (Tappenden et al. 2012).

Of the RCTs exploring the effects of PHVs on older peoples' use and costs of services, those performed among the oldest olds (mean age over 80 years) seemed more probable to produce beneficial effects on the use of services compared with those performed among the younger old population (Fairhall et al. 2015, Imhof et al. 2012, Melis et al. 2008, Stuck et al. 1995, Stuck et al. 2000). This is in contrast to some earlier reviews that have suggested that younger populations of older people would benefit more (Huss et al. 2008, Stuck et al. 2002). However, earlier reviews have mostly explored clinical outcomes, and been focused less on the use and costs of services. Older people's use of demanding healthcare and social services increases towards the end of their lives (Luppa et al. 2010, Ní Chróinín et al. 2018). As younger populations of older people are less likely to be hospitalized or institutionalized, showing a difference in use of services might be harder or require larger power in studies with participants consisting of younger older people.

Most of the studies that have shown favourable effects on use and costs of services have been conducted on participants with fairly good functional status. Only three out of ten studies showing positive effects on use of services were targeted to older people with functional decline at the start of the study (Fairhall et al. 2015, Melis et al. 2008, Shapiro et al. 2002). An earlier review revealed similar results suggesting that older people with relatively good functional status would benefit the most from PHV interventions (Stuck et al. 2002).

The number of home visits varied in the studies from one to over ten. The RCTs with four or more home visits more often produced beneficial effects on the use of services by the participants (Fairhall et al. 2015, Hendriksen et al. 1984, Imhof et al. 2012, Melis et al. 2008, Shapiro et al. 2002, Stuck et al. 2000, Stuck et al. 1995, van Rossum et al. 1993). This finding supports the results of earlier research suggesting that the intensity of the intervention might influence its effectiveness (Stuck et al. 2002). In the present trial, the intensity of PHV intervention, with three home visits, may have been too low and more intensive intervention or support during follow-up might have influenced the effects and their stability during follow-up.

In the present RCT the use of healthcare and social services by the intervention and control groups was balanced at baseline. Although the intervention group showed lower total costs, with the intervention costs included, the difference in the total costs of services was not statistically significant. This may be because the distribution of use and costs of services is often distinctly positively skewed (Briggs et al. 1998b). Showing a statistically significant difference between groups in costs of services might have required a larger number of participants than was included in the present RCT, the power of which was calculated on the basis of the primary outcome, HRQoL (15D measured) (Briggs et al. 1998b).

The findings in the PHV intervention trial concerning total costs were similar to those in earlier studies exploring the effects of PHV interventions on total costs of healthcare and social services. None of the RCTs showed significant differences in total costs between intervention and control groups (Brettschneider et al. 2015, Fairhall et al. 2015, Kono et al. 2016, Melis et al. 2008, Metzelthin et al. 2015, Ploeg et al. 2010, Sahlen et al. 2008, Schraeder et al. 2001, Stuck et al. 1995, Stuck et al. 2000, van Rossum et al. 1993).

Although there were no statistically significant differences in QALYs gained and total costs of healthcare and social services, the cost-utility analysis showed 60% of the ICERs lying in the "dominant" quadrant of the cost-effectiveness plane. These results suggest that the intervention would possibly be superior to typical care offered by the municipality, being both more effective and less expensive (Briggs et al. 1998a). Of the earlier RCTs that presented ICERs on a cost-effectiveness plane to evaluate cost-effectiveness of the intervention, one revealed that the probability of the intervention to be "dominant" was 34.6%, and the level at which the intervention would be cost-effective was a willingness to pay 34,000 euros (Melis et al. 2008). In contrast to the findings of the present RCT, one trial revealed the intervention not to be cost-effective, with only a 2% probability of the intervention being "dominant" when calculating ICERs (Metzelthin et al. 2015). Both of these earlier RCTs were targeted to participants with functional decline at the start of the trial, which might be one reason for the less favourable results compared with those in the present PHV trial. Furthermore, if the measures used in these trials to detect the effect of the intervention were not sensitive enough in the target group of older people, the cost-effectiveness of the intervention might have been underestimated (Huter et al. 2016).

6.5 Strengths and limitations of the study

The systematic literature review was conducted according to the guidelines on systematic reviews (Cochrane Handbook 2006, 2011, Moher et al. 2015). The inclusion criteria were determined before the search for and selection of studies. The review was based on a comprehensive search of RCT articles from databases and supplemented with a manual search for potential articles from the reference lists of relevant reviews. The flowchart of the study was presented to demonstrate the screening and selection of the studies. However, the review was conducted on published results only, which may have resulted in publication bias, influencing the results towards positive effects.

The methodological quality of the studies was evaluated for risks of bias. Most of the trials were of good or moderate methodological quality. Of the studies included, four were of poor methodological quality, and three of them reported some positive effects. Thus, these results may be biased as a result of poor study methodology. The results of these studies were included in the systematic review for transparency, with mention and discussion of their poor quality.

The heterogeneity of the PHV trials is a limitation in the present systematic review. The variety of interventions, target groups and outcomes measured and reported hindered comparison of the studies. Pooling of the data or performing a meta-analysis was not seen to be justified because of the heterogeneity of the studies. This has been earlier discussed in several reviews, which have stated the problems of pooling data from a variety of interventions and outcomes and the average effects of meta-analyses potentially underestimating the effects of complex interventions (Lin et al. 2012, Toljamo et al. 2005, Van Haastregt et al 2000). The heterogeneity of the studies creates a challenge in detecting the key elements of the trials leading to positive results. Although many of the trials were designed to be practicable, the generalizability of the study results has to be evaluated in the context of the healthcare settings in which they originally took place.

Some factors in the RCTs might lead to underestimation of the effects of the interventions. Some trials had a relatively low power (Crawford Shearer et al. 2010, Dalby et al. 2000, Granbom et al. 2017, Shapiro et al. 2002), so they might not show the potential effectiveness of the PHV interventions adequately. Many of the studies involved light intervention. Although some of these studies produced some favourable results (Behm et al. 2016, Byles et al. 2004 McEvan et al. 1990, Frese et al. 2012, Gunner-Svensson et al. 1984, Gustafsson et al. 2012, Kono et al. 2012, Sahlen et al. 2006, Vetter et al. 1984), others did not show any positive effect (Metzelthin et al. 2015, Sorensen et al.1988). The light interventions might have decreased the efficacy of these trials.

Our PHV intervention targeted to older people had several strengths. It was a randomized, controlled trial with few exclusion criteria. The study had good power, with 422 participants randomized into two study arms and the groups were balanced at baseline. The PHV intervention programme was carefully planned and designed to be practicable and transferrable to other primary-care contexts. The primary outcome measure, HRQoL (15D instrument) is clinically meaningful and well validated for older people. The 15D measure has proven to be sensitive to changes after intervention. The dropout rate in the analyses of HRQoL and QALYs was relatively low, with 88% of the intervention group and 85% of the control group having at least two 15D measurements included in the analysis. The data on use and costs of healthcare and social services were collected in detail. Finnish registers for mortality are 100% complete, and the healthcare and social services are reliably registered in medical and social services' records and central registers. A true intention-to-treat analysis was performed in connection with the use of healthcare and social services of the participants and the costs involved. No adverse effects of the intervention were recorded.

The multiprofessional PHV intervention was one strength of the study. The intervention included CGA, which has been shown to be effective in multifactorial interventions targeted to older people in earlier research (Dhesi et al. 2018, Ekdahl et al. 2016, Stuck et al. 2002). The intervention was semi-structured, with oral and written instructions to the professionals delivering it. Validated measures were used in the comprehensive assessment performed as part of the intervention. The intervention was individualized according to the needs of the participant. There were no drop-outs during the intervention, and all intervention visits were delivered according to plan. The PHV intervention was well received by the participants.

The PHV trial has some limitations. The participants and deliverers of the intervention could not be blinded due to the nature of the trial, which exposes the study to a risk of bias. At the time of analysis the data was not blinded, although the analyses were performed following the intention-to-treat principle. The light intervention protocol was practicable, but it might be less effective than more intensive PHV interventions. The participants were motivated volunteers, which is a common characteristic of RCTs. However, this might diminish the generalizability of the results to the general population. The Hawthorne effect cannot be ruled out as one dimension of the positive results on HRQoL among the intervention participants through the attention they received from the interveners. Although the trial included a large number of participants, the power might not have been large enough to detect differences in mortality or in total costs to the healthcare and social services.

7 Conclusions

A systematic review of RCTs exploring the effects of PHV interventions targeted to older people suggested that the intervention produces some favourable effects on functioning, well-being and HRQoL, and mortality in a cost-neutral manner. However, the results were varied and the target groups benefitting most, as well as the elements of interventions producing the beneficial effects remain mostly unclear. There is a scarcity of research on the cost-effectiveness of PHV interventions.

Based on the results of the systematic review of the RCTs, older people (over 80 years of age) of relatively good functional status might benefit the most from PHV interventions, when considering the effects on use of healthcare and social services. It seems that including CGA in the assessment and intervention is crucial in producing favourable effects. Interventions with four or more home visits and sufficient follow-up and support during follow-up might be more effective than lighter or shorter interventions, especially in producing favourable effects on the use and costs of healthcare and social services.

A large RCT was conducted among independent community-dwelling older people, exploring the effects of multiprofessional PHV intervention on their HRQoL (15D measure) and use and costs of healthcare and social services. HRQoL declined significantly more slowly in the intervention group compared with the control group during the first year of follow-up, but the effect became diluted and was no longer significant at the two-year follow-up. The participants of this RCT were older people with fairly good functional status.

No significant differences in mortality, QALYs gained or total costs between the groups were observed. Although there were no significant differences in total costs, 60% of the ICERs lay in the "dominant" quadrant of the cost-effectiveness plane, suggesting that the intervention might be more effective and less costly than normal care. Thus, the conclusion is that the favourable effects on HRQoL were achieved cost-neutrally.

8 Clinical and future implications

Although PHV interventions have been studied widely and also in large, good-quality RCTs, findings on their effectiveness remain controversial. Favourable effects on functioning, well-being and HRQoL, and mortality have been suggested in a variety of studies. However, studies with HRQoL and cost-effectiveness as outcomes are scarce. In addition, multiprofessional PHV interventions have been promising but less well studied. Prior PHVs have been mostly focused on older people's morbidities and disabilities. Thus, they often lack resource-oriented and positive approaches to older people. Therefore, all these elements in PHV trials still need to be studied. Future studies should be targeted to relatively well functioning older people who are probably more likely to benefit from PHV interventions. Furthermore, the manner of support during follow-up and the required intensity of such support should be further studied. Research should focus on PHV interventions with sufficient intensity and support during follow-up. In addition, future studies should be based on implementation of CGA, which has shown effectiveness in earlier studies targeting older people. CGA includes a resource-oriented approach and aims to empower older people and support their coping.

Several PVH trials have shown favourable effects. However, pragmatic implementation studies are needed in order to explore real-life effectiveness in various populations and countries. Researchers should describe the target groups, interventions and outcomes in detail in order to enable evaluation and comparison of PHV interventions and their effects. Large, possibly multi-centre studies on PHVs might produce new information on the effectiveness of PHV interventions and their key elements.

Since PHVs have already shown several positive effects among older people, they should be implemented in primary care more widely. When disseminating PHVs in Finland, older people (over 80 years of age) with fairly good functional status seem to benefit the most from PHV interventions in regard to use and costs of healthcare and social services. Furthermore, interventions of sufficient intensity (≥ four home visits) delivered by interprofessional teams are more likely to produce favourable effects. If a PHV intervention is designed to reduce rates of institutionalization or hospitalization, it should be targeted to fairly independent older people of more advanced age and the intervention should be of sufficient intensity. CGA with a resource-oriented approach should be used and professionals sufficiently educated to implement CGA.

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Appendices

Appendix 1. List of questionnaires included in baseline and follow-up postal surveys.

Appendix 2. Additional questions in baseline and follow-up postal surveys.

Appendix 3. List of measures used during nurse home visit.

Appendix 4. List of measures used during physiotherapist home visit.

Appendix 5. List of measures used during social worker home visit.

Appendix 1. List of questionnaires included in baseline and follow-up postal surveys.

1. Ikihyvä:
   Fogelholm Mikael, Haapola Ilkka, Absetz Pilvikki, Heinonen Heikki, Karisto Antti, Kasila Kirsti, Mäkelä Tiina, Seppänen Marjaana, Talja Martti, Uutela Antti, Valve Raisa ja Väänänen Ilkka. Ikihyvä Päijät-Häme -tutkimus. Perusraportti 2005. https://www.researchgate.net/publication/242260507_IKIHYVA_PAIJAT-HAME_-TUTKIMUS_Perusraportti_2005 ; 2005 [accessed 16.1.2019]
2. 15D:
   Sintonen H. The 15D instrument of health-related quality of life: properties and applications. Ann Med 2001;33:328-336.
3. List of medications in use and a short questionnaire on risks of potential harms of medications.
4. Additional questions:
   See Appendix 2.

Appendix 2. Additional questions in baseline and follow-up postal surveys.

LISÄKYSYMYKSET

66. Tupakoitteko nykyisin, eli poltatteko savukkeita, sikareita tai piippua?

1 En
2 Kyllä
3 Olen lopettanut ____ vuotta sitten

67. Asun

1 Omakotitalossa
2 Rivitalossa
3 Kerrostalossa
4 Muu, mikä ?_____

68. Kotona liikkuminen on helppoa ja esteetöntä

1 Kyllä
2 Hieman vaikeuksia
3 Paljon vaikeuksia

69. Mistä liikkumisvaikeudet kotona johtuvat? Kirjoita vastauksesi vapaamuotoisesti alla olevaan tilaan.

70. Asumisympäristössä liikkuminen on helppoa

1 Kyllä
2 Hieman vaikeuksia
3 Paljon vaikeuksia

71. Mistä liikkumisvaikeudet asuinympäristössä johtuvat? Kirjoita vastauksesi vapaamuotoisesti alla olevaan tilaan.

72. Pituuteni on ____ cm

73. Painoni on ___ kg

Vastaajan puhelinnumero:

Vastaajan sähköpostiosoite:

Appendix 3. List of measures used during nurse home visit.

Physiological measurements: blood pressure, blood glucose

The Barthel index (ADL):

Mahoney FI, Barthel DW. Functional evaluation: The Barthel index. Md State Med J 1965;14:61-65.
http://www.thl.fi/toimia/tietokanta/mittariversio/84/

Geriatric Depression Scale GDS-15:

de Craen AJ, Heeren TJ, Gussekloo J. Accuracy of the 15-item geriatric depression scale (GDS-15) in a community sample of the oldest old. Int J Geriatr Psychiatry 2003;18:63-66.
http://www.thl.fi/toimia/tietokanta/mittariversio/87/
Measure available (in Finnish) at: http://www.muistiasiantuntijat.fi/media-files/testit/GDS-15.pdf [accessed 17.1.2019]

Lawton scale (IADL):

Lawton MP, Brody EM. Assessment of older people: Self-maintaining and instrumental activities of daily living. Gerontologist 1969;9:179-186.
http://www.thl.fi/toimia/tietokanta/mittariversio/31/
Measure available (in Finnish) at:
http://www.thl.fi/toimia/tietokanta/media/files/mittariversio/2012/06/11/IADL_lomake_toimia.pdf [accessed 17.1.2019]

Mini Mental State Examination MMSE:

Folstein MF, Folstein SE, McHugh PR. Mini-mental state. A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res 1975;12:189-198.
http://www.thl.fi/toimia/tietokanta/mittariversio/91/
Measure available (in Finnish) at: http://www.muistiasiantuntijat.fi/media-files/testit/MMSE_150210.pdf [accessed 17.1.2019]

MNA:

Guigoz Y, Lauque S, Vellas BJ. Identifying the elderly at risk for malnutrition. The mini nutritional assessment. Clin Geriatr Med 2002;18:737-757.
Measure available (in Finnish) at: http://www.muistiasiantuntijat.fi/media-files/testit/mna_mini_finnish.pdf [accessed 17.1.2019]

RAI-HC:

Morris JN, Fries BE, Bernabei R, Steel K, Gilgen R, DuPasquier JN, Fritzer D, Henrard JC, Hirdes JP. RAI-Home Care (RAIHC) Assessment Manual for version 2.0. Boston: InterRAI, 1999.

Appendix 4. List of measures used during physiotherapist home visit.

Falls Risk of Older People, FROP-Com screen:

Russell MA, Hill KD, Blackberry I, Day LM, Dharmage SC. The reliability and predictive accuracy of the falls risk for older people in the community assessment (FROP-com) tool. Age Ageing 2008;37:634-639.
Measure available (in Finnish) at:
https://thl.fi/documents/966696/1449811/Lyhyt_kaatumisvaaran_arviointi_FROP-Com.pdf/fd90661a-bbcf-48e6-8c0b-968a02c5ad06 [accessed 17.1.2019]

Hand Grip Strength Jamar:

Abizanda P, Navarro JL, Garcia-Tomas MI, Lopez-Jimenez E, Martinez-Sanchez E, Paterna G. Validity and usefulness of hand-held dynamometry for measuring muscle strength in community-dwelling older persons. Arch Gerontol Geriatr 2012;54:21-27.
http://www.thl.fi/toimia/tietokanta/mittariversio/141/
Instructions for measuring available (in Finnish) at:
http://www.thl.fi/toimia/tietokanta/media/files/mittariversio/2013/04/11/TOIMIA_suoritusohje_kaden_puristusvoima.pdf
Reference values available (in Finnish) at:
http://www.thl.fi/toimia/tietokanta/media/files/mittariversio/2019/01/14/Puristusvoima_viitearvot_2017_TOIMIA_ID041.pdf

A chair-stand test, 5 times:

Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: Association with self-reported disability and prediction of mortality and nursing home admission. J Gerontol 1994;49:85-94.
http://www.thl.fi/toimia/tietokanta/mittariversio/155/
Instructions for measuring available (in Finnish) at:
http://www.thl.fi/toimia/tietokanta/media/files/mittariversio/2014/03/10/TOIMIA_tuoliltanousu5x_suorituso hje.pdf
Reference values available (in Finnish) at:
http://www.thl.fi/toimia/tietokanta/media/files/mittariversio/2014/03/05/TOIMIA_tuoliltanousutesti_viitearvot.pdf

Appendix 5. List of measures used during social worker home visit.

The Barthel index (ADL):

Mahoney FI, Barthel DW. Functional evaluation: The Barthel index. Md State Med J 1965;14:61-65.
http://www.thl.fi/toimia/tietokanta/mittariversio/84/

Lawton scale (IADL):

Lawton MP, Brody EM. Assessment of older people: Self-maintaining and instrumental activities of daily living. Gerontologist 1969;9:179-186.
http://www.thl.fi/toimia/tietokanta/mittariversio/31/
Measure available (in Finnish) at:
http://www.thl.fi/toimia/tietokanta/media/files/mittariversio/2012/06/11/IADL_lomake_toimia.pdf [accessed 17.1.2019]

RAI-HC:

Morris JN, Fries BE, Bernabei R, Steel K, Gilgen R, DuPasquier JN, Fritzer D, Henrard JC, Hirdes JP. RAI-Home Care (RAIHC) Assessment Manual for version 2.0. Boston: InterRAI, 1999.

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